IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION (at Cincinnati)

LISA CONLEY 38 Ash Street Ludlow, KY 41016 **Plaintiff,** v.	:	**Case No.** _____ **Judge** _____
ABUBAKAR ATIQ DURRANI, M.D., Serve: Orthopedic & Spine Institute 203 Canal Road Lahore 54000 Pakistan (Serve by regular mail) and **WEST CHESTER HOSPITAL, LLC** 7700 UNIVERSITY DRIVE WEST CHESTER, OH 45069 SERVE: GH&R BUSINESS SVCS., INC. 511 WALNUT STREET 1900 FIFTH THIRD CENTER CINCINNATI, OH 45202 (Serve via Certified mail) and **UC HEALTH** SERVE: GH&R BUSINESS SVCS., INC. 511 WALNUT STREET 1900 FIFTH THIRD CENTER CINCINNATI, OH 45202 (Serve via Certified mail) and **CENTER FOR ADVANCED SPINE TECHNOLOGIES, INC.** Serve: Orthopedic & Spine Institute 203 Canal Road Lahore 54000 Pakistan	:	**COMPLAINT FOR DAMAGES WITH JURY DEMAND ENDORSED HEREON**

(Serve by regular mail) :
:
and :
:
CHRIST HOSPITAL :
2139 AUBURN AVENUE :
CINCINNATI, OHIO 45219 :
:
SERVE: CT CORPORATION :
SYSTEM :
1300 EAST NINTH STEET :
CLEVELAND, OHIO 44144 :

Plaintiff, Lisa Conley, for her *Complaint for Damages with Jury Trial Demand Endorsed Hereon* (the "Complaint) against defendants Abubakar Atiq Durrani, M.D., and West Chester Hospital, LLC and UC Health and Center for Advanced Spine Technologies, Inc. and Christ Hospital (together, the "defendants"), states and alleges as follows:

I. PARTIES.

1. The incidents giving rise to this action and the subject matter of the Complaint arise out of medical treatment, fraud, acts and omissions, and conduct that occurred in Hamilton County, Ohio.
2. At all times relevant, Plaintiffs were residents of and domiciled in the State of Kentucky.
3. At all times relevant, Dr. Abubakar Atiq Durrani (hereinafter "Dr. Durrani") was licensed to and did in fact practice medicine in the State of Ohio.
4. At all times relevant, Center for Advanced Spine Technologies, Inc. (hereinafter "CAST"), was licensed to and did in fact perform medical services in the State of Ohio, and was and is a corporation authorized to transact business in the State of Ohio and Kentucky.
5. At all times relevant, West Chester Hospital, LLC (hereinafter "West Chester Hospital"),

was a limited liability company authorized to transact business and perform medical services in the State of Ohio and operate under the trade name West Chester Hospital.

6. At all times relevant, Defendant UC Health Inc., was a duly licensed corporation which owned, operated and/or managed multiple hospitals including, but not limited to West Chester Hospital, and which shared certain services, profits, and liabilities of hospitals including West Chester.
7. At all times relevant herein, West Chester Medical Center, Inc., aka West Chester Hospital held itself out to the public, and specifically to Plaintiffs, as a hospital providing competent and qualified medical and nursing services, care and treatment by and through its physicians, physicians in training, residents, nurses, agents, ostensible agents, servants and/or employees.
8. UC Health is the corporate parent, owner and operator of West Chester Hospital, LLC.

II. JURISDICITON AND VENUE.

1. UC Health Stored BMP-2 at UC Health Business Center warehouse located in Hamilton County.
2. UC Health is the corporate parent, owner and operator of West Chester Hospital, LLC. UC Health is located in Hamilton County making Hamilton County appropriate to bring this lawsuit.
3. At all times relevant, The Christ Hospital ("TCH") was a limited liability company authorized to transact business and perform medical services in the State of Ohio and operating under the trade name The Christ Hospital.
4. The amount in controversy exceeds the jurisdictional threshold of this Court.
5. This Court is thus the proper venue to grant Plaintiff the relief sought.

6. This Court has jurisdiction based upon diversity under 28 U.S.C. § 1332.

III. FACTS.

1. Plaintiff first sought treatment with Dr. Durrani for her neck, head, upper back, and mid back pain.
2. Dr. Durrani recommended surgery for the Plaintiff.
3. On or around October 26, 2006, Dr. Durrani performed surgery on Plaintiff at Christ Hospital. Upon information and belief, Dr. Durrani performed a cervical spinal fusion.
4. Plaintiff went to follow up care at Children's Hospital and complained of no improvement in her pain.
5. Dr. Durrani recommended a second surgery.
6. Dr. Durrani performed a second surgery at Christ Hospital on or around February 7, 2007. Dr. Durrani operated on Plaintiff's cervical spine and thoracic.
7. At follow- up care Plaintiff complained of no improvement in her pain; Dr. Durrani recommended a third surgery.
8. On or about May 26, 2010, Dr. Durrani performed a spinal fusion from Plaintiff cervical spine to her thoracic at West Chester Hospital/ UC Health.
9. Upon information and belief, Dr. Durrani used Infuse/BMP-2 "off-label," without Plaintiff's knowledge or consent, causing Plaintiff harm.
10. The use of BMP-2 increases a person's chance of cancer by 3.5%.
11. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

12. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of cancer. As a result, Plaintiff has an increased fear of cancer.
13. After the third surgery, Plaintiff was in significant pain.
14. Plaintiff continued to go to follow-up care, at CAST, until Dr. Durrani fled the country.
15. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.
16. As a direct and proximate result of this surgery and Dr. Durrani's negligence, the Plaintiff has suffered harm.
17. Plaintiff did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel informed Plaintiff of Dr. Durrani's propensity to use BMP-2.

WEST CHESTER/UC HEALTH

1. West Chester/UC Health failed to report a single incident of any kind involving Dr. Durrani to the National Practitioner Data Bank and any other reporting agency including the Ohio Medical Board despite there being countless required reports.
2. According to HRSA Data, 42% of hospitals have never made a single report to NPDB.
3. With respect to Dr. Durrani, West Chester/UC Health did not follow their written medical staff policies and procedures under their professional practice evaluation policy.
4. West Chester/UC Health failed to follow the triggers for peer review from January 2009 through May 2013.
5. The following are the triggers for peer review or other actions as provided by West Chester/UC Health to the Deters Law Office in discovery in related litigation and is a list

which by their own admission is not exclusive and is a list they produced after full knowledge of the items Dr. Keith Wilkey, Plaintiffs' experts, considered triggers:

a. Wrong operative procedure performed

b. Serious injury due to medical device

c. Procedure performed on wrong patient

d. Medication resulting in death

e. Delay in diagnosis

f. Autopsy not correlated with clinical diagnosis

g. Delay in treatment resulting in serious injury or death

h. Alleged abuse or neglect

i. Unexpected death

j. Surgical death

k. Mortality review

l. Unplanned second surgeon called to OR

m. MD not credentialed for procedure

n. Focus review

o. Incident reports

p. Contraindication to surgery

q. Unintended retention of foreign object in a patient after surgery

r. Complications from procedure (i.e. readmits, infections, pneumothorax after procedure)

s. X-ray discrepancies

t. Returns to surgery

u. Transfusion not meeting criteria on order sheet

v. Change in surgery/procedure

w. Laceration/or perforation/puncture of organ during invasive procedure

x. Acute MI or CVA within 48 hours of procedure

y. Anesthesia complications

z. MD without timely response to ED or unit call

aa. Risk management issues

bb. Delay in treatment not resulting in serious injury and/or death

cc. Delay in diagnosis not resulting in injury or death

dd. Acute blood loss as indicated by procedure

ee. Appropriate care measures not ordered

ff. Readmission- complication of previous admission

gg. Unplanned admission following surgery

hh. 72 hours returns to ED and readmit same issue

ii. Insufficient documentation

jj. BMP-2

kk. PureGen

ll. Late dictation or no dictation of operative reports or discharge summaries

mm. False claim of spondylolisthesis

nn. False claim of stenosis or its severity

oo. Performing surgeries on patients whose health condition vitiates surgery:

1. Age, diabetes, obesity, hypertension, mental health issues, etc.

pp. Shanti Shuffle- Dr. Shanti being forced to do an entire surgery for Dr.

1. Durrani by Dr. Durrani without the patient's knowledge.

qq. No hospital consents or improper CAST consents

rr. Failed Hardware

ss. Performing surgery not qualified to perform

tt. Dura tear

uu. Having hardware which should be removed, which is never removed

vv. Not using the proper cage with BMP-2

ww. Ignoring radiology results

xx. Misrepresentations to primary care physicians

6. Dr. Keith Wilkey, a board-certified spine expert, has reviewed over 400 patient charts at West Chester of Dr. Durrani and signed over 400 affidavits of merit as required under CR10 of Ohio Rules of Procedure to file a medical malpractice case and based upon these reviews over 500 events triggers place which would have required action against Dr. Durrani by West Chester. Defendants intentionally took no action.
7. From January 2009 through May 2013, with respect to Dr. Durrani, Defendants failed to follow their Medical Staff Code of Conduct which they approved as witnessed by Ed Crane, President of the Medical Staff and Paula Hawk.
8. Unknown Defendants include all Members of the Executive Committee, Credentialing Committee and Peer Review from 2009 through 2013.
9. Article I of the MEC bylaws gives the MEC "oversight," of quality of care and patient safety for West Chester.
10. Article 3.1.1 sets forth who the officers are including President, Director of Surgery, Director of Medicine and Chair of Credentials Committee.

11. Article 3.3.1 provides the duties of each department director and Article 4.4 provides the functions of the department.
12. Defendants have refused to produce through discovery the members of West Chester's Medical Executive Committee, Credentialing Committee and Peer Review Committee from 2009 through 2013.
13. Plaintiff did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel informed Plaintiff of his propensity to use the drug.

MORE SPECIFIC ALLEGATIONS BASED UPON DISCOVERY AND DEPOSITION TESTIMONY

1. Krissy Probst was Dr. Durrani's professional and personal assistant handling professional, academic, travel, surgery scheduling, his journals, his Boards, his credentialing, his personal affairs and his bills.
2. Krissy Probst worked as Dr. Durrani's assistant for three years at Children's Hospital from 2006, 2007, and 2008.
3. Krissy Probst reported Dr. Durrani to Sandy Singleton, the Business Director at Children's for his having an affair with Jamie Moor, his physician assistant.
4. Krissy Probst resigned in 2008 from Dr. Durrani and remained working for three other surgeons in the Orthopedic Department.
5. Krissy Probst worked in the Orthopedic Department for eleven years from 2002-2013. She retired in May 2013.
6. Krissy Probst confirmed Dr. Durrani claims being a Prince, when he is not.
7. According to Krissy Probst, Dr. Crawford, an icon in pediatric orthopedics treated Dr. Durrani "like a son."

8. According to Krissy Probst, Dr. Crawford, Chief of Orthopedics at Children's unconditionally supported Dr. Durrani no matter the issues and problems Dr. Durrani faced.
9. Dr. Durrani's patient care at Children's Hospital dropped off considerably after Jamie Moor became his physician assistant and they began their affair.
10. Dr. Durrani was the only orthopedic spine surgeon at Children's who would perform a dangerous high volume of surgeries.
11. At Children's, Dr. Durrani would begin a surgery, leave and have fellows and residents complete a surgery or do the full surgery while he was in his office with Jamie Moor, his physician assistant for four or five hours.
12. Children's Board and administration knew about Dr. Durrani doing too many surgeries and not properly doing the surgeries. They did nothing.
13. Dr. Durrani argued to Children's administration when they complained to him that he made them money so Children's tolerated him and allowed him to do what he wanted.
14. Dr. Durrani, when told by Children's that Jamie Moor had to leave, told Children's that he would leave too.
15. Dr. Agabagi would do one spine patient a day at Children's because it takes normally eight hours for a full fusion.
16. Dr. Durrani would schedule two to three spine surgeries a day at Children's.
17. Dr. Durrani would repeatedly have the Business Director, Sandy Singleton, or OR Director allow him to add surgeries claiming they were emergencies when they were not.

18. Dr. Durrani would leave a spine surgery patient for four or five hours in the surgery suite under the care of fellows or residents, unsupervised and sit in his office and check on the surgery as he pleased.
19. Dr. Peter Stern did not like Dr. Durrani while Dr. Durrani was at Children's because he knew all about his patient safety risk issues. Yet, Dr. Stern supported, aided and abetted Dr. Durrani's arrival at West Chester. It defies comprehension, but was for one of the world's oldest motives—greed of money.
20. There is also a Dr. Peter Sturm, an orthopedic at Children's who also had no use for Dr. Durrani.
21. Dr. Durrani chose his own codes for Children's billing which he manipulated with the full knowledge of Children's Board and management.
22. Dr. Durrani was dating and living with Beth Garrett, a nursing school drop-out, with the full knowledge of his wife Shazia.
23. Dr. Durrani was close with David Rattigan until David Rattigan pursued Jamie Moor and Dr. Durrani would not allow David Rattigan in the OR at Children's for a long time.
24. Dr. Durrani, while claiming to have riches, does not. Dr. Durrani's wife's family paid for Dr. Durrani's education and it is her family with the significant wealth.
25. Medtronics paid for Dr. Durrani's trips and paid him $10,000 fees for speaking or simply showing up at a spine conference.
26. Krissy Probst's business director told her to save all Dr. Durrani related documents and information and she did.
27. While doing research at Children's, Dr. Durrani would misstate facts regarding his research. Children's knew he did this.

28. Dr. Durrani ended on such bad terms with Children's Hospital he was not allowed on the premises after his departure in December 2008, yet he performed a spine surgery there in February 2009.
29. Eric J. Wall, MD was the Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.
30. Sandy Singleton, MBA was the Senior Business Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.
31. On information and belief, Dr. Durrani used his relationships with Children's officials to purge his Children's file of all patient safety and legal issues which had occurred as part of his departure "deal" which Defendants hide with privilege.
32. Defendants committed fraud by misrepresenting Dr. Durrani's reputation. Defendant knew he was doing unnecessary spine surgeries and concealing them from Plaintiffs. With the intent to mislead Plaintiffs, and knowing Plaintiffs would rely upon the misrepresentations and concealment, Defendant caused harm to Plaintiffs. Defendant knew their false information regarding Dr. Durrani was material to Plaintiffs decision making in choosing Dr. Durrani as a surgeon, allowing him to perform surgery, following his recommendation and being trusting to have their procedures at Defendant hospitals.
33. Dr. Durrani's CAST website states in part: "The entire focus at CAST is on the patient. From the ease in getting in to see a physician…to wellness, therapy and treatment programs that can help patients avoid surgery…to minimally invasive techniques if surgery is necessary…to our remarkable facility and one-site convenience. It's time patients have the level of preventive care and advanced treatment we offer. Atiq Durrani, MD- Founder of CAST." As shown and will be shown, this is a material

misrepresentation which is false relied upon by Dr. Durrani's patients including Plaintiffs to allow Dr. Durrani to perform unnecessary surgeries on Plaintiffs.

34. Gerry Goodman worked under a Corporate Integrity Agreement in 2010 at West Chester/UC Health.

35. Gerry Goodman, from August to November 2010, while serving as the interim director of OR nursing at West Chester Medical Center, complained to administration including Mitch McCrate about Dr. Durrani's deviations and violations of law, policies, bylaws, rules and regulations which were effecting patient care, including Plaintiffs.

36. Mitch McCrate told Gerry Goodman West Chester/UC Health wasn't concerned because "the hospital had state funding and therefore was not held to qui tam rules."

37. Gerry Goodman told Mitch McCrate, General Counsel; Jack Talbot, HR; George Caralis, COO and Kevin Joseph, MD, President; that Dr. Durrani had a "partner" who had not received provider status and Dr. Durrani was billing his "partner" under Dr. Durrani's provider number, something which was illegal.

38. The "partner" was Dr. Shanti.

39. Dr. Durrani and Dr. Shanti would do three or four cases simultaneously and bill them simultaneously.

40. Gerry Goodman told McCrate, Talbot, Caralis and Joseph she could not work in a place which condones illegal practices. They asked her to ignore them. She refused.

41. Dr. Durrani, according to Gerry Goodman, did whatever he wanted in the OR and knew he could get away with it including being treated like a king by the vendors.

42. Vendors such as Medtronic representatives were allowed in the OR after going through the preapproved process they must go through. David Rattigan, Dr. Durrani's primary vendor, worked at Bahler peddling Medtronic products.
43. Dr. Durrani was abusive to his and West Chester/UC Health staff. This was tolerated by West Chester/UC Health and effected patient care including that of Plaintiffs.
44. Dr. Durrani never cared about other schedules or the West Chester/UC Health OR schedule.
45. Dr. Durrani declared every surgery an emergency to ignore schedules.
46. Dr. Durrani received two full days and two half days of block time at West Chester/UC Health. It was never enough time for his over utilization.
47. When Gerry Goodman would say no to a Dr. Durrani scheduling request, Dr. Durrani would contact West Chester/UC Health administration and she would be overridden.
48. Gerry Goodman had skill, knowledge and experience to recognize a "Dr. Durrani" because she had been involved in the outing of another over-utilizer and unnecessary procedure surgeon performing cardiac catherizations.
49. Spine surgeons usually do one or two a day, possibly three surgeries a day if an emergency.
50. Dr. Durrani would often do four, five and even six surgeries.
51. Dr. Durrani and Dr. Shanti would walk from surgical room to surgical room with all the spine patients "open" for an extended time past the standards of care.
52. On at least two occasions, Dr. Durrani patients were open for in excess of an hour waiting for him to come into the case.

53. When Gerry Goodman would complain to Dr. Durrani about patients being under anesthesia and the operative site open for long periods of time, Dr. Durrani would claim "we are covering anesthesia with antibiotics."

54. When Dr. Durrani performed with Dr. Shanti these multiple simultaneous procedures, they were billed as if he was the attending surgeon in all three surgeries.

55. The Dr. Shanti and Dr. Durrani "open and switch" to do the surgery, we have labeled the "Shanti Shuffle."

56. The Shanti Shuffle is not the normal. Shanti did not assist, he replaced.

57. Gerry Goodman complained to risk management repeatedly to no avail of the Shanti Shuffle.

58. When Gerry Goodman pointed out to risk management, Jill Stegman and David Schwallie that Dr. Durrani had all the "red flags" from over utilization and being bounced out of other area hospitals, they responded "how did you know." Gerry Goodman knew because anyone in hospital administration and management in the tristate in 2008 to 2013 knew. Dr. Durrani was no secret.

59. Jill Stegman and David Schwallie admitted to Gerry Goodman they knew about Dr. Durrani's over utilization, being "bounced out" of other hospitals and all the issues going on with him with the OR, but West Chester needed Dr. Durrani's numbers.

60. When Gerry Goodman complained to George Caralis about Dr. Durrani, he told Gerry Goodman to "keep your mouth shut and go back to work because you are just an interim."

61. George Caralis told Gerry Goodman that West Chester/UC Health needed Dr. Durrani surgeries and admissions and therefore they were not going to stop him.

62. Jill Stegman and David Schwallie informed Gerry Goodman they would get back with her about Dr. Durrani in a few days. They never did.

63. After Gerry Goodman was blown off by David Schwallie and Jill Stegman, she decided to leave her work assignment at West Chester/UC Health.

64. Gerry Goodman checked the written consents of BMP-2 patients including Plaintiffs which Dr. Durrani, CAST and West Chester/UC Health had them sign and confirmed they did not provide consent to BMP-2.

65. Gerry Goodman reported on the lack of consent for BMP-2 also to Schwallie, Stegman, Joseph, Caralis, Talbot and McCrate and they ignored her.

66. Gerry Goodman verified there was nothing in the patients' charts, including Plaintiffs' charts, reflecting they were informed of the risks of off label use of BMP-2.

67. Upon hearing her repeated complaints about Dr. Durrani, George Caralis told Gerry Goodman she was just an "emotional female."

68. Gerry Goodman reported to no avail patient safety issues caused by the OR staff working from 7 AM to midnight on Dr. Durrani patients. Fatigue caused deviations in standard of care by West Chester/UC Health staff's including in Plaintiffs.

69. No action was taken by West Chester/UC Health's board or management to correct the informed consent issue on BMP-2. The time period of Gerry Goodman's warning and complaints were fall 2010. Plaintiffs' claims arise from January 1, 2009 through May 2013. At least, according to Gerry Goodman's interim service, any Plaintiff having BMP-2 placed after the fall of 2010 at West Chester/UC Health is a further tragedy because the Board, administration and management can't obey notice and they allowed Dr. Durrani to continue placing BMP-2 at will. Why? Money. Despite having full

knowledge of the issue, West Chester/UC Health's board and management allowed patients including Plaintiffs to have BMP-2 placed in them by Dr. Durrani at their facility without warning them, with full knowledge they were not warned.

70. Gerry Goodman knew anesthesia charged per the minute or in fifteen-minute increments and she considered it a fraud to bill for unnecessary anesthesia when patients were "open" longer than necessary.

71. Dr. Durrani would contact Medtronics and other vendors directly; they would bring into the OR what Dr. Durrani requested and then invoice West Chester/UC Health.

72. During surgeries, Medtronics and other vendors would want to up sell products.

73. This process was distracting to the OR staff and affected patient care.

74. Dr. Durrani told Gerry Goodman Dr. Shanti had privileges, but wasn't yet on all the insurance panels.

75. Gerry Goodman asked Dr. Durrani: "Which panel so he's not doing those cases?"

76. Dr. Durrani told Gerry Goodman in response: "We're doing these procedures together. They're billed under my name."

77. Gerry Goodman witnessed one case where Dr. Durrani was never in the room at all, just Dr. Shanti. Yet, Dr. Durrani claimed the procedure.

78. Gerry Goodman confronted Dr. Shanti and he simply stated: "Dr. Durrani and I are co-surgeons."

79. Gerry Goodman verified Dr. Shanti was not on the written informed consents for these procedures.

80. Kevin Joseph, MD, and President of West Chester Medical Center, knew everything Gerry Goodman complained about because either she told him or George Caralis told him. Caralis told her he told him.
81. Dr. Durrani had no supervision at all at West Chester/UC Health.
82. When Gerry Goodman attempted to supervise him, the West Chester/UC Health management as described here rebuked her.
83. Gerry Goodman also informed Mitch McCrate, Jill Stegman, David Schwallie, George Caralis and Kevin Joseph, MD, that Dr. Durrani's high volume of fusions of the spine was not usual practice. They ignored these concerns.
84. West Chester/UC Health's board and management did not provide proper supervision of Dr. Durrani as required through the surgery and orthopedic departments. (See Bylaws section to follow)
85. Gerry Goodman also spoke to the Chief of Surgery at West Chester Medical Center about Dr. Durrani to no avail.
86. The West Chester/UC Health manager who did analytics and kept records sent to Gerry Goodman at her request, months' worth of their BMP tracking. She kept it and still has it.
87. West Chester/UC Health has previously denied tracking BMP-2. They lied. They tracked it to analyze the profit. They liked the profit. They encouraged Dr. Durrani to place all the BMP-2 he could.
88. Based upon Gerry Goodman's documentation, Plaintiffs have requested and expect to receive all BMP-2 tracking as evidence of Plaintiffs BMP-2 claims.

89. West Chester/UC Health's board and management increased the cost of the surgeries of Plaintiffs and patients by using BMP-2 infuse.

90. Dr. Durrani would also sign operative reports he never dictated with the full knowledge of West Chester/UC Health's board and management. This is yet another practice Gerry Goodman complained about.

91. Kate Fenner, PhD, owner of Compass Clinical Consulting, told Gerry Goodman that she had a meeting approximately 2007/2008 at West Chester Hospital with Kevin Joseph to alert him to Durrani's billing and medical practices. Kate Stated that she knew Dr. Durrani was leaving prescriptions unsigned for his office nurses to distribute as needed when he was out of the country. Kate then stated that she knew Kevin knew about the questionable billing practices and was told **"WE NEED THE CASES AND THE REVENUES."**

92. Dr. Shanti dictated operative reports he never signed with the full knowledge of West Chester/UC Health's board and management. They knew because Gerry Goodman complained.

93. Orthopedics and spine surgeries are some of the highest sources of income for a hospital and were too for West Chester/UC Health.

94. In the spring of 2013, Dr. Peter Stern told Dr. Angelo Colosimo, UC Orthopedic Surgeon that West Chester/UC Health "knew all about Dr. Durrani's issues before he came to us and after he came to us, but we needed the money."

95. The billings for Dr. Durrani surgeries were sent to Plaintiffs at their homes with requests for payment.

96. Plaintiffs were required to make payments of uncovered medical bills to Dr. Durrani and CAST.

97. Dr. Durrani produced, distributed and utilized a video of a lecture involving his EDS patients to solicit more patients.

98. Unbeknownst to his EDS patients, Dr. Durrani was doing experiments on these EDS patients including many of the Plaintiffs without informing them they were part of an experiment. This too violated West Chester Medical Staff Bylaws as revealed in a later section.

99. Dr. Durrani claims in his EDS video a 95% success rate with the C1-C2 operations and only one of the twenty-five claimed they would not have the surgery again.

100. The undersigned counsel represents 20 of these 25 persons and not one would have the surgery again. They are Plaintiffs.

101. Dr. Tayeb was an employee of Dr. Durrani from 2009 to 2013. Counsel has interviewed him extensively.

102. Dr. Tayeb will testify that Dr. Durrani improperly selected patients for surgery, and then recommended surgery, including patients with EDS that were not proper candidates for surgery including many of the Plaintiffs.

103. Dr. Tayeb will testify that improper business practices occurred at CAST, including Dr. Durrani recommending surgeries that were medically unnecessary including the Plaintiffs.

104. Dr. Tayeb will testify that Dr. Durrani made decisions to place wealth and status over the well-being of his patients including Plaintiffs.

105. Dr. Tayeb, Dr. Durrani's pain management doctor for a time at CAST, reports that Dr. Durrani's misuse of BMP-2 resulted in bony overgrowth, where "it's like a big block of bone back there where you can't even stick a needle there anymore" and patients, including Plaintiffs would develop neuropathic pain.

106. Dr. Tayeb could not reach the nerve in many of the BMP-2 patients to even treat with injections.

107. Dr. Tayeb would engage Dr. Durrani in shouting matches at CAST over patient care that others witnessed.

108. According to Dr. Tayeb, Dr. Durrani would not always speak truthfully about patients having already gone through conservative care.

109. According to Dr. Tayeb, Dr. Tayeb believes West Chester knew about Dr. Durrani's prior issues.

110. According to Dr. Tayeb, surgical notes were not being done timely and there are some "clinical ramifications."

111. According to Dr. Tayeb, many times surgeries were performed in different areas than the work up.

112. According to Dr. Tayeb, patients would not understand what Dr. Durrani was doing.

113. According to Dr. Tayeb, Dr. Durrani loved to tell patients he would "fix" them.

114. According to Dr. Tayeb, Dr. Durrani told patients they would be paralyzed.

115. According to Dr. Tayeb, Dr. Durrani exaggerated the diagnosis of lumbar degenerative disc disease and stenosis.

116. According to Dr. Tayeb, ER patients with back pain were referred to Dr. Durrani.

117. According to Dr. Tayeb, he heard about West Chester facing financial challenges.

118. According to Dr. Tayeb, he is of the opinion Risk Management knew about Dr. Durrani issues.

119. According to Dr. Tayeb, Paula Hawk at a meeting with Dr. Durrani, Dr. Tayeb and Brian Gibler (CEO UC Health said: "We work with Dr. Durrani. We cater to Dr. Durrani, you know, to point where we want to try to expedite and make everything easy for you guys to bring everything over here." "He's our partner in crime."

120. According to Dr. Tayeb, there were a suspicious high number of spine surgeries.

121. According to Dr. Tayeb, Dr. Durrani bragged in the halls he was the top money maker.

122. According to Dr. Tayeb, he's aware of at least one time four (4) surgery suites reserved at one time for Dr. Durrani.

123. According to Dr. Tayeb, West Chester advertised they were a premier spine institute.

124. According to Dr. Tayeb, there was a discussion about CAST and West Chester co-oping and Dr. Durrani wanted a "piece" of the action.

125. According to Dr. Tayeb, there were $100 a day fines for records over 30 days late. He has no idea if Dr. Durrani was fined.

126. According to Dr. Tayeb, Dr. Durrani went an entire six months—no records.

127. According to Dr. Tayeb, there were also issues of too long of days in surgery.

128. According to Dr. Tayeb, Dr. Durrani had two heart attacks and would get sick, go to ER get fluids and keep operating.

129. According to Dr. Tayeb, Dr. Tayeb believes Dr. Joseph had to have knowledge of the issues.

130. According to Dr. Tayeb, Dr. Durrani was super aggressive.

131. According to Dr. Tayeb, seen in clinic to surgery scheduling was for 30 patients 20-30% for Dr. Durrani.

132. According to Dr. Tayeb, others for 30- one or two scheduled.

133. According to Dr. Tayeb, Dr. Durrani would schedule surgeries without looking at MRI or ordering one.

134. According to Dr. Tayeb pertaining to Dr. Durrani, "I think it was just everything that was walking needed to be cut on in some way, shape or form whether it was necessary or not."

135. According to Dr. Tayeb, Defendants held discussions with Dr. Durrani regarding using 4th floor of hospital for CAST rehab.

136. According to Dr. Tayeb, lack of documentation effects patient care and West Chester responsible.

137. According to Dr. Tayeb, he heard the "paralyze" and "severe stenosis" to patients from Dr. Durrani a lot.

138. Elizabeth Dean was employed at West Chester Medical Center before they opened the doors for business.

139. Elizabeth Dean was one of the original patient access representatives at West Chester Medical Center, which is now West Chester Hospital, beginning employment in February 2008 to July 2010.

140. Elizabeth Dean had many responsibilities within the hospital including admitting Dr. Durrani patients and completing financial reports for the West Chester/UC Health CFO, Mike Jeffers.

141. Elizabeth Dean was also included in most corporate meetings where discussions took place over the mass injections performed by Dr. Durrani in the testing area of the hospital and she also was the actual patient access representative who registered and spoke with all the Durrani patients.

142. According to Elizabeth Dean, before Dr. Durrani began to practice at West Chester Hospital, every area of the hospital was a "ghost town."

143. Despite being a new hospital, it was still not picking up revenue as it expected.

144. Elizabeth Dean was required to ask for all copays when the patients arrived, just to "keep the numbers up" as much as possible.

145. Elizabeth worked for five years as a medical biller with University Internal Medicine Associates before coming to West Chester.

146. Elizabeth Dean knew West Chester/UC Health needed money based upon her position and work at West Chester.

147. Elizabeth Dean reviewed the final numbers from CFO Mike Jeffers each month and also logged all payments received on the surgery cases including Dr. Durrani's.

148. West Chester/UC Health's board and management gave staff raises based upon the hospitals financial woes.

149. West Chester/UC Health fired the original CEO and corporate employees once the hospital was bought by UC Health, and appointed an ER physician as the new CEO, Kevin Joseph, MD.

150. Elizabeth Dean will testify that West Chester/UC Health decided to have West Chester/UC Health ran by physicians.

151. Vickie Scott worked at West Chester in the operating room during the time Dr. Durrani also worked there.

152. OR Nurses, including Vickie Scott, went to the OR management, Elaine Kunko and Denise Evans and to Risk Management, Jill Stegman, about Durrani's illegal activities, deviations in standard of care and violations of policies, bylaws, regulations and rules. No action was taken. They complained and reported the same issues Gerry Goodman reported as previously described.

153. Vickie Scott informed Elaine Kunko, OR assistant manager, about Dr. Durrani making the records appear that Dr. Durrani was doing all the procedures when they knew it was Dr. Shanti. Kunko did nothing to stop the Shanti Shuffle.

154. Scott Rimer, circulating nurse at West Chester Medical Center, spoke up and complained about Dr. Durrani at an OR meeting with OR staff and hospital administration. Not only was Scott Rimer ignored, the next day he had his supervisor standing next to him watching his every move. He was fired soon after.

155. In summary, Gerry Goodman, Vickie Scott, Scott Rimer and other OR staff members complaints to management included the number of Dr. Durrani surgeries he did a day and at a time; other surgeons performing surgeries for him without proper consent; Dr. Shanti not having proper qualifications and provider numbers; BMP-2 was tracked by the hospital despite their denials of doing so; Dr. Durrani was verbally abusive to everyone; anesthesiologists had to have patients "under" longer than they should have been; off label use of BMP-2 was not covered by informed consent; Medtronic reps

would "up-sale" during surgeries; operative reports were not timely completed; Dr. Durrani had no supervision by the hospital; keeping OR staff past the time it was safe.

156. Those Gerry Goodman, Vickie Scott, Scott Rimer and other OR staff members complained to included Mitch McCrate, Jack Talbot, George Caralis, Kevin Joseph, MD, Melissa Hemmer, Elaine Kunko, Denise Evans, Jill Stegman, and David Schwallie. All of these individuals are and/or were West Chester/UC Health management who communicated these complaints to the board. Many like Kevin Joseph, MD, President were on the board.

157. West Chester/UC Health, its board and management, also knew of Dr. Durrani's sexual harassment of OR nurses and staff and ignored it.

158. Melissa Dowler witnessed Dr. Durrani offer a nurse in the OR $10,000 for oral sex.

159. Dr. Durrani had an affair with his staff member, Beth Garrett, who dropped out of nursing school, and like his relationship with a prior physician assistant at Children's Hospital, Jamie Moor it affected patient care.

160. Dr. Durrani, by his deposition testimony, admits he relies upon his own reading of radiology. Of course, in this manner he would recommend a surgery the radiology did not support. The radiology department at West Chester, the director of radiology and all the radiologists privileged at West Chester from January 1, 2009 to June 1, 2013, knew Dr. Durrani was ignoring their radiology interpretations and did nothing to address the issue and/or were ignored when they tried to address the issue.

161. Dr. Durrani, by his deposition testimony, admits he informs the pain doctor where to inject medicine. By doing so in the wrong place, he convinced many Plaintiffs to have repeat surgeries.

162. Melissa Garrett is forty-one (41) years old, and is a pharmaceutical salesperson in Tampa, Florida. Melissa Garrett said her sister Elizabeth "Beth" Garrett who worked for Durrani/CAST.

163. Melissa Garrett contacted counsel and stated that Beth Garrett was holding herself out as a nurse, although Beth Garrett had failed out of nursing school.

164. Melissa Garrett stated that Beth Garrett had been present during surgeries by Dr. Durrani.

165. She stated that Beth Garrett had improperly assisted in surgical procedures performed by Dr. Durrani without a nursing license.

166. She stated that Beth Garrett had been improperly selling pharmaceutical products, without a license.

167. She stated that Beth Garrett was having an "affair" with Dr. Durrani, and that she was concerned after Beth Garrett brought Dr. Durrani to her son's elementary school function and that the family "freaked out" in response to Beth Garrett and Dr. Durrani's conduct during the school function.

168. Dr. Durrani prescribes a custom compound cream he sells to patients without informing them which he bills to their insurance and just sends to them.

169. On information and belief Dr. Durrani owns some interest in this compound cream in a physician owned distributorship (POD) arrangement.

170. Shauna O'Neal followed Gerry Goodman to West Chester as Director of Nursing.

171. Shauna O'Neal came from Compass Clinical Consulting group in Cincinnati.

172. Shauna O'Neal wrote a letter to Tom Daskalakis the COO of West Chester/UC Health, Kevin Joseph, MD, and the CNO in which in which she reiterated what Gerry Goodman reported regarding Dr. Durrani's OR bookings and Dr. Shanti's lack of credentials and/or privileges. She was ignored.

173. Thomas Kunkel, MD, anesthesiologist, complained to West Chester/UC Health's board and management about Dr. Durrani's high number of "add on" patients. He was ignored.

174. According to Gerry Goodman, Dr. Durrani did add on patients at the last minute and after regular business hours so there was no one to preauthorize patients or question Durrani in any way regarding the surgery.

175. Dr. Durrani always told Thomas Kunkel, MD the surgeries were emergencies.

176. At times anesthesiology demanded the Chief of Surgery to intercede to judge whether or not it was emergent.

177. Cindy Traficant was Periop Director before and after West Chester opened.

178. When UC Health took over, Julie Holt, the original CNO, quit.

179. Cindy Traficant became interim CNO.

180. Cindy Traficant had a reputation of tolerating "bad" physicians.

181. West Chester Surgery was nicknamed by staff at West Chester/UC Health the "island of misfit" doctors because they took in and tolerated any doctor no matter their ethics, including Dr. Durrani.

182. OR staff collectively reported Dr. Durrani issues to West Chester/UC Health board and management and their complaints were ignored.

183. Dr. Durrani would sometimes, because he was running behind, cancel part of a surgery or do only part of the surgery, thus requiring the patient to have another surgery, all without informing the patient the cancellation was because he was late.

184. Dr. Durrani performed 159 surgeries at West Chester Medical Center in 2009; 534 in 2010; 536 in 2011; 437 in 2012; and 157 in 2013 for a total of 1,823 surgeries.

185. West Chester/UC Health admitted in a discovery answer in the *Shell* case that for the investigation, background check and the information used to decide to grant Dr. Durrani privileges they relied upon in part:

- Dr. Durrani's education.
- Dr. Durrani's training and experience.
- Copies of his licenses and DEA numbers.
- Inquiry to the National Practitioners Data Bank.
- Evidence of required continued education.

186. West Chester/UC Health refuses to provide under a claim of privilege all persons they consulted prior to permitting Dr. Durrani privileges.

187. Dr. Durrani total **surgeries** performed as answered in a discovery in *Shell* at West Chester is as follows:

2009: 665

2010: 1908

2011: 1736

2012: 1102 (Through 9/30/12)

188. Dr. Durrani admitted as **inpatient** based as answered in a discovery answer in *Shell* at West Chester is as follows:

2009: 154

2010: 488

2011: 507

2012: 305 (Through 9/30/12)

189. Dr. Durrani admitted as outpatients based as answered in a discovery answer in *Shell* at West Chester is as follows:

2009: 13

2010: 41

2011: 45

2012: 35 (Through 9/30/12)

190. West Chester/UC Health refuses to provide under a claim of privilege their investigation to determine Dr. Durrani's fitness to practice medicine prior to permitting Dr. Durrani privileges.

191. West Chester/UC Health refuses to provide under claim of privileges, the instances where Dr. Durrani did not follow proper medical documentation protocol, policies and/or procedures at West Chester/UC Health.

192. West Chester/UC Health refuses to provide under claim of privileges, the complaints made by employees, staff or patients related to Dr. Durrani.

193. Dr. Durrani oftentimes used PureGen when performing surgeries, if this case involves PureGen, this is noted within this Plaintiff's specific factual allegations addressed earlier in this Complaint.

194. PureGen has never been approved by the FDA for any human use. It's also now off the market for any use.

195. Doctor Atiq Abubakar Durrani used the product PureGen in his capacity as a medical doctor in spines in the same manner BMP-2 was used.

196. West Chester/UC Health assisted Dr. Durrani in his use of PureGen at their facility.

197. A representative from Alphatec Spine was in the operating room during medical procedures per the Nursing Intraop Records when Dr. Durrani used PureGen.

198. A representative from Alphatec Spine was in the operating room during medical procedures even when the Nursing Intraop Records do not indicate so.

199. Dr. Durrani was and is a paid consultant for Alphatec Spine.

200. Dr. Durrani has an ownership stake in the Alphatec Spine.

201. Dr. Durrani provided PureGen to patients who required surgery and those who did not require surgery without Plaintiffs knowledge and consent.

202. Dr. Durrani performed unnecessary surgeries using PureGen on his patients.

203. West Chester Hospital, UC Health and the Center for Advanced Spine Technologies knowingly created false medical records, bills, and cost reports that included charges for unlicensed uses of PureGen, which resulted in inflated outlier payments to be paid by the government and other insurers using the Plaintiffs' right to make a claim; or in the alternative, causing a false cost reports.

CHRONOLOGICAL FACTUAL ALLEGATIONS

1. On January 1, 2009, Durrani opened the Center for Advanced Spine Technologies (CAST).

2. In February of 2009, Elizabeth Dean began working at West Chester where she prepared reports for Mike Jeffers on Dr. Durrani's billings. She testified Mike Jeffers was excited about what he read on the spreadsheets.
3. In February of 2009, Mike Jeffers, Director of Finances joined West Chester (He stays until January 2012). The director of finance admitted West Chester/UC Health tracked Dr. Durrani's financial numbers. He admits Dr. Durrani helped them in their "time of need." Dr. Durrani was the highest money generator. He knew Dr. Durrani had more than one surgical suite assigned at once. Bonuses were paid on finances.
4. In February of 2009, Carol King, Senior VP, joined West Chester. She ran it before Dr. Joseph. She would stay until April 7, 2010. She was discharged and testified: "They didn't want me there anymore." Carol King was the first person in charge of West Chester was fired and ordered by counsel not to disclose the reason. She was a patient safety-first thinker. She did not explore the "rumors" about Dr. Durrani's leaving Children's.
5. In May of 2009, Medical Staff Office Policies and Procedures were adopted by West Chester (Peer Review) - Paula Hawk, Director of Medical Staff and Ed Crane, President of Medical Staff.
6. In May of 2009, Dr. Tim Kremchek, MD joined the staff of West Chester. He remains. He's always been the Director of Orthopedics. The Chief of the Orthopedic department failed to do his job under the MEC bylaws as it related to Dr. Durrani. He knew Dr. Durrani was a "sloppy" spine surgeon, yet did nothing.
7. In May of 2009, Elaine Kunko joined West Chester from the beginning. She remains. She has held various jobs from daily operations coordinator of OR to Asst. Nurse

Manager. She's now a coordinator in quality management. She testified West Chester knew about Dr. Durrani not completing records. They knew Dr. Durrani would claim surgeries were emergency. They knew there was an issue with Dr. Durrani not being in the room doing surgery on "his" patient. Even the OR nurses knew they put up with Dr. Durrani for money. West Chester tracked Dr. Durrani's numbers.

8. In May of 2009, West Chester Hospital opened.
9. In May of 2009, Vickie Scott began working at West Chester Hospital.
10. In May of 2009, Dr. Durrani was privileged at West Chester.
11. In June of 2009, AAOS Advisory on Consent BMP-2 (Off-Label) was published. West Chester/UC Health received it.
12. On July 7, 2009, a warrant was served to Dr. Durrani for assault of his wife. West Chester/UC Health learned of this fact.
13. The surgery schedule of Dr. Durrani shows an overwhelming number of surgeries Dr. Durrani was doing to the delight of the officers, management, Board of West Chester and Defendants. It's to support all claims.
14. The chronological sequence further fulfils the requirements under R.C. 2305.251 that Defendants knew of Dr. Durrani's "pattern of incompetence," "otherwise inappropriate behavior" and "fraudulent medical treatment" and their fraud.
15. On September 2, 2009, Jane Dresselhaus emailed Rohlfing and Hawk regarding a complaint about Dr. Durrani not doing progress notes.
16. On September 7, 2009, Rohlfing sent an email to Durrani – "Dr. Durrani – We have not been seeing progress notes on your patients and the patient below is one example.

Obviously, this is a JCAHO and 3rd party requirement of many payors. Please help us avoid the exposure of these violations. Thank you – Ron."

17. On September 8, 2009, Ron Rohlfing sent an email to Dr. Durrani- Complaint- "We have not been seeing progress notes on your patients…"
18. On October 5, 2009, Elaine Kunko emailed Marc Feldman, Carol King, Cyndi Trafficant, Ann Simpson- Informing Dr. Durrani is buying products off contract- Orthovita, Trans One, Vitoss, Vitagel, AxiaLIF, Interventional Spine, Perpose, X Close, X2M.
19. On October 26, 2009, Paula Hawk sent an email and copied to Ron Rohlfing, Gina Witko and Cyndi Trafficant regarding a complaint that Dr. Durrani did not timely discharge patients.
20. In 2009, West Chester's Net Loss was $13,319,102.00.
21. In 2009, there were 159 total West Chester Durrani Surgeries for the year.
22. In 2009, Lesley Gilbertson, MD left West Chester.
23. On March 5, 2010, Elaine Kunko sent an email to Debbie Blimline and copied to Denise Evans. Complaint- Dr. Durrani not marking a surgical site before bringing the patient into OR.
24. On April 7, 2010, Carol King, Senior VP was fired.
25. On April 8, 2010, Kevin Joseph, M.D. becomes President of West Chester. He also is on the ER staff there. He's also a Senior VP of UC Health. He remains in these positions. Per his deposition: The CEO claims to know nothing about surgery operations is his hospital. The CEO claims a hospital must protect patients from unnecessary harm "as much as they can." The CEO claims they don't have oversight of surgeons doing what all plaintiffs claim Durrani was doing (despite what his bylaws state). The CEO denies

the hospital has any responsibility if Dr. Durrani did an unnecessary surgery. The CEO, despite his finance office tracking it, denies any knowledge of BMP-2 use. The CEO denies knowing about any complaints about Dr. Durrani. The CEO admits they benefited financially from Dr. Durrani, including his own pay.

26. On June 2, 2010, there was an email between Blimline and Joseph-"Just wanted to let you know that Dr. Durrani admitted two patients today and deemed them emergency procedures for tomorrow, Saturday 2/3/10. We have recruited extra people to do back up call for the OR as this will tie the OR call team up from approximately 0800-1500. I have consulted with Rosemary Kiser who is aware of the plan."
27. In July 2010, Elizabeth Dean left her employment at West Chester.
28. On July 2, 2010, there was an email from Joseph to Blimline- "Thanks for the heads up and keeping me in the loop. Do you know diagnosis and what makes them emergent operations? We should certainly keep track of these.
29. On July 2, 2010, there was an email from Blimline to Joseph-"HIPAA- Diagnosis Lumbar DDD, Lumbar Spinal Stenosis, and Procedure: Direct Lateral Interbody Fusion, L3-L4, posterior spinal fusion, L3-4, L4-L5 Laminectomy. I do not know the symptoms these patients are having that could possibly make them emergent. I do know he wanted to have the day scheduled tomorrow and we are not ready to grant that at this time. Yesterday in a meeting it was determined by George, Cyndi, and Rosemary that all of the costs would be considered before granting him Saturday time and this was communicated to his office yesterday when they tried to schedule this Saturday. I know there are other surgeons who have wanted Saturday time. My concern is if we offer it to Dr. Durrani for

a few Saturdays and cover it with all staff (including anesthesia) on OT then other Drs. will also expect this to happen for them."

30. On July 2, 2010, there was an email from Joseph to Blimline- "Thank you for the info. I called Durrani to discuss urgency and explain significant cost implications, logistical implications with call team and also lifestyle implications with call team. Thank you for making me aware."
31. On July 2, 2010, there was an email from Blimline to Joseph/Trafficant/Rosemary Keiser- "I appreciate your follow up. I have a correction to make about the earlier information. The patients were admitted on Wed and they were told their cases would be on Saturday. This came from (Kathy/Melissa H.)
32. On August 2010, Gerry Goodman begins as Interim Director of Nursing in Operating Room at West Chester.
33. On August 6, 2010 Brian Isaacs, Medical Record Transcriptionist, informs law firm Santen & Hughes that Dr. Durrani privileges are suspended until his charts are completed (West Chester). Brian Isaacs confirms this suspension through at least October 5, 2010.
34. On August 23, 2010, there was an email from Gerry Goodman to Yvette Kauffman, Cyndi Trafficant, Debbie Blimline- "Durrani wants it a full day's schedule. States he has already booked 5 cases (which of course, he has not). He wants either to proceed with Monday cases or schedule them for the Saturday before. Your view?"
35. On August 27, 2010, there was an email from Goodman to Kauffman, Trafficant, Blimline, Willenborg, Parker, Kunko- "Please be aware that reps support Dr. Durrani have been bringing in trays "just in case." Dr. D does a case the Saturday before Labor Day. Sounds a little suspect to me."

36. On September 16, 2010, there was an email from Cyndi Trafficant to Kathy Lebowitz and Reply Same: Complaint Dr. Durrani wanted air cast splint. OR refused. He went to ED. Registered himself as patient and got an air cast.
37. On September 21, 2010, Durrani was still suspended, according to Isaacs.
38. On September 23, 2010, there was an email from Cyndi Trafficant to Kevin Joseph and Paula Hawk: Complaint- Durrani cases ran long and had to call in on call team. Resulted in another doctor taking a surgery to another place. "Schedules know that they are not to take Durrani's office staff word for how long a case will take." "Durrani played the system last night and stuck the team."
39. On October 5, 2010, Dr. Durrani still suspended at West Chester, according to Brian Isaacs.
40. On October 26, 2010, emails between Debbie Blimline and Cyndi Trafficant, Rosemary Keiser, Kevin Joseph regarding a complaint that Dr. Durrani runs late on cases outside his block.
41. On October 26, 2010, there was an email from Kevin Joseph, M.D. to Trafficant and Blimline- "For now, we will be sticking with the current scheduled, until 7 PM. With that said we know that he has a habit of running late, which I am going to talk to him about and try to get under control. Also make sure the schedulers are using his average time of cases, not the time his office says it takes to do his cases. I agree with Cyndi, that if you want to schedule the staff on his days until 9 PM, so that they are scheduled instead of last minute late ending, then it may add job satisfaction to our nurses. At this time, we will not be extending hours until 11 PM."
42. In 2010, West Chester's Net Loss was $5,195,431.00.

43. In 2010, there were 534 total West Chester Durrani Surgeries for the year.
44. On February 10, 2011, there was a letter to Pam Kinane, Patient Advocate- copied to Kevin Joseph- 4 Pages- Complaint from Parent Regarding Dr. Durrani- Serious Care Issue.
45. On April 6, 2011, there was an email from Hanner to Cyndi Trafficant and Karen Ghaffari: Complaint- Dr. Durrani failed to see his patients- unhappy. "In addition, it raises the question if their medical needs were addressed."
46. In May 2011, Jeff Drapalik CFO joined West Chester. He is currently still there.
47. On May 4, 2011, there was an email from Jennifer Krause to mtaylor@castworld.com copy Wendy Gilkey- Complaint on four cases with insurance pay issues: 1. No operative report dictated. 2. "There is no MRI report or H&P to justify why this patient had this procedure." 3. There is no dictation. 4. No dictation.
48. On May 18, 2011, there was an email from Kevin Joseph to Mike Jeffers- Complaint about Dr. Durrani on hospital eating expenses on a case. Email from Paula Hawk to Kevin Joseph and Mike Jeffers- Complaint about Dr. Durrani -delinquent dictations, no clinical documentation, Aetna denial, Op notes are supposed to be dictated within 24 hours in our bylaws," My daily conversations with Dr. Durrani don't seem to be working.
49. In July 2011, the Medical Staff Office Policies and Procedures Adopted- West Chester (Peer Review).
50. On September 14, 2011, there was an email from Stegman to Joseph, Daskalakis, Rohlfing and Hawk reporting a lawsuit being filed against Dr. Durrani.
51. On October 15, 2011, there was an email from Janet Thompson to many including Hawk. "There was a patient that was going to go to 1 pct and at 2243 they said Dr. Durrani

insisted that the patient go to 3 pct even though they were infected. That meant that 1 pct was to lose a nurse. I told them that they had to send a nurse home by 2 a.m. if they did not get an admission. Thanks, Janette E. Thompson MSN, RN Clinical Supervisor UC Health-West Chester Medical Center.

52. In 2011, West Chester's Net Loss was $8,365,918.00.

53. In 2011, there were 536 total West Chester Durrani surgeries for the year.

54. On January 2012, Mike Jeffers, Director of Finance, left West Chester.

55. On February 2, 2012, there was an email from Tom Blank to Durrani and Marc Feldman and Thomas Harris at UC Health- "Thanks for your time on the phone this morning to discuss Dr. Durrani's request for spine implant products. Back in November when we first submitted formulary pricing, we included all the Alphatec Spine products and met or exceeded your formulary pricing. FYI, since that time we have added products from Spinal USA per Dr. Durrani's request. Please verify that you have all the Spinal USA information. Dr. Durrani and Dr. Shanti have been utilizing the Alphatec Spine biologics including PureGen and Profuse. We are able to provide a great savings with many of the biologics products while providing implants that are approved per the indication and safe for use. After you speak to Tom Harris, I look forward to talking with you in regards finalizing the agreement. As mentioned, the terms and conditions have been signed, the pricing met and all necessary papers have been submitted. I am at the ready to supply anything you need to move forward and take care of Dr. Durrani's request. Thanks again for your time and consideration as we look forward to furthering our relationship.

56. On April 19, 2012, Dr. Durrani had a seminar at West Chester (Claimed he was an Assistant Professor at UC and Children's when he is neither. West Chester allows this to happen.)

57. On May 16, 2012, there was an email from Heather Waugh to Debbie Blimline, Mark Tromba and Virginia Craig. Complaint- "post op sheets not being signed and orders not being completed." "This is difficult to track MDs down to do orders, while taking care of two patients."

58. On May 17, 2012, there was an email from Mark Tromba to Heather Waugh, Debbie Blimline and Virginia Craig- "I know that the reason it has happened to Dr. Durrani is because his partner has not been here certain days to do his dirty work. This is going to continue and I have talked to Dr. Durrani." "Most of the physicians are compliant." "Please let Ginney or I know about the issue when it happens again. (Because I know it will)." "Dr. Durrani has been addressed many times. What is the next step?" (Blimline response).

59. On July 6, 2012, there was an email from Kathie Hays to Mark Tromba- "He bold face lies. Does Kevin and Patrick know?"

60. On July 6, 2012, there was an email from Tromba to Hays- "Durrani screwed us over! Lied to Patrick and I about the patient being in too much pain to fly… the patient is having surgery tomorrow at his surgery center…. And one our instruments are going to!!! Kevin is being notified… not much else. Have a great rest of your trip! See you Monday!

61. On July 6, 2012, there was an email from Tromba to Hays-"Yeah, I asked him why his patient canceled for today and he said he couldn't fly because he was in so much pain.

Yet was currently on a flight to Cinci. Patrick said he would address it with senior leadership… I'll update you on Monday!"

62. On July 20, 2012, UC Health began purchasing PureGen from Evolution Medical, LLC.

63. On August 6, 2012, there was an email from Kathie Hays to Virginia Craig and Mark Tromba- "It's a shame Durrani was actually here on time for the first time and we weren't able to get the patient started."

64. On August 6, 2012, there was an email from Joseph to Daskalakis – "Reporting new lawsuit being filed."

65. On August 27, 2012, there was an email from Tromba to Hays – Subject: RE: Attendance Certificate – Well Managed OR "Do I still get this even though we were talking to Durrani about cussing out Amy??"

66. On August 29, 2012, there was an email from Tom Blank to Griggs- RE: Evolution Alphatec Spine Par Level. Attachment: Evolution Medical West Chester MedAssets Biologics Par Level 071312.

67. On October 4, 2012, there was an email from Tom Blank to Willenborg and Griggs- "Yesterday, Paula asked me to help her find a PureGen vial and track it. I was able to track where the item was used and the patient's name. I don't have Paula's email or number so I hope you can help here. Item 67010-050. Lot vial #AS3000 31470 Implanted HIPAA L5-S1 Fusion. Please confirm and let me know how this helps."

68. On October 4, 2012, there was an email to Griggs to Tom Blank- "I send the info to Paula, thanks for following up and thanks again for the heads up on the VToss."

69. On December 16, 2012, there was an email from Griggs to Sheldon & Hays- "Gary – Several of our Spine surgeons are consistently using Medtronic Magnifuse Bone Graft.

The Rep. Dave Rattigan has been bringing this in for the surgeons to use for approximately one year. Since Infuse it not being used, our usage of Magnifuse has increased. To ensure the product is here, when we need it, we want to keep it on our shelf. Dave can supply us a Pyxis to keep the Magnifuse in. Also, this would be very helpful in tracking the bone product. I spoke with Kathy and she ok'd the Pyxis but would like to run it by you before I give Dave the OK. Please let me know. Thank you, Becky

70. On December 19, 2012, there was an email from Sheldon to Griggs, Hayes and Dwayne Brown "Becky – UC Health's standard practice is not to accept equipment from suppliers. If additional clarification is needed, I recommend contacting Dennis Robb's office.
71. In 2012, West Chester's Net Loss was $8,366,000.00.
72. In 2012, there were 437 total West Chester Durrani surgeries for the year.
73. On January 2013, Dr. Thomas Brown left West Chester as Chief of Radiology.
74. On January 24, 2013, there was an email from Joseph to Durrani- "Atiq – I hope all is well with you, your family and your practice. Can you please review the below email and take some time to complete the below deficiencies ASAP. I know completing medical records is the most painful part of our jobs (I hate it too), but prompt medical record completion is needed for financial as well as mediolegal reasons. Thanks, Atiq. KJ (This matter involved a chart missing, a d/c summary and a $119,098.45 claim BWC would not process without it.)
75. On February 8, 2013, UC Health stops purchasing PureGen from Evolution Medical, LLC.

76. On March 6, 2013, there was an email from Tammy Benzinger to Tromba, Hays, Hawk, Stephens, and Talbot. "Today I was at the surgical desk and an employee stated to me that Dr. Durrani is going to get himself in a lot of trouble. He called an employee "Mexican" all the time and had just called another employee a Jew. As part of management team I felt I needed to pass this information along to the team. Thanks, Tammy."
77. In May 2013, the Policy "Stop the Line" Adopted at WCH.
78. In May 2013, Paula Hawk states West Chester begins a policy: "Stop the Line" A policy called "stop the line" was implemented the same year and month they kicked out Dr. Durrani. Paula Hawk admits at her deposition money is not supposed to trump patient safety. She admits peer review is for hospitals to protect each other. She admits hospitals are interested in volume, something Dr. Durrani provided.
79. On July 22, 2013, Federal Criminal Complaint against Dr. Durrani was filed.
80. On July 25, 2013, Dr. Durrani was arrested for Health Care Fraud and Making False Statements.
81. On July 27, 2013, Elizabeth Dean emailed Eric Deters providing information regarding Dr. Durrani at West Chester.
82. On August 2, 2013, Vickie Scott emailed Eric Deters providing information regarding Dr. Durrani at West Chester.
83. On August 7, 2013, Dr. Durrani was indicted.
84. On September 13, 2013, Dr. Durrani performed surgery on Dolores Scott, at WCH (Our last known Dr. Durrani surgery at West Chester. We were informed he left in May.)

ADDITIONAL ALLEGATIONS ON THE ISSUE OF STATUTE OF LIMITATIONS, STATUTE OF REPOSE AND FRAUD REGARDING WEST CHESTER

1. From the time of the surgery and/or surgeries Dr. Durrani performed on Plaintiff, to the end of his treatment of Plaintiff, through his flight from the United States in November 2013, Dr. Durrani lied to Plaintiffs' primary care physician and directly to Plaintiff about the outcome of the surgery. Dr. Durrani informed Plaintiff and Plaintiffs' primary care physician the surgery was successful and perfect, knowing the surgery on Plaintiff was a failure.
2. Dr. Durrani, from the date of his surgery until his flight in November 2013, had a duty to inform Plaintiff of the truth about the unsuccessful surgery and failed to do so.
3. Dr. Durrani also failed to disclose to Plaintiff not only that he placed BMP-2 in Plaintiff without their consent, but he failed to place BMP-2 with the proper cage resulting in ectopic bone growth and other ongoing harm to Plaintiff which is ongoing to this day.
4. Dr. Durrani also lied to Plaintiff about the results of post-op radiology which reflected the failure of the surgery. Nor did he order additional radiology to properly evaluate Plaintiff's condition from after the surgery through his flight in November 2013.
5. Dr. Durrani never revealed hardware failure to Plaintiff from after the surgery through his flight in November 2013.
6. West Chester/UC Health knew Dr. Durrani practiced all of this deception described in the five prior paragraphs and did not disclose it to the Plaintiff. Dr. Durrani's and West Chester/UC Health's duties to Plaintiff with information they knew did not end with Dr. Durrani leaving West Chester/UC Health.
7. Dr. Durrani and West Chester/UC Health intentionally left BMP-2 off all their consent forms so Plaintiff would not know it was placed in their spine.
8. West Chester/UC Health concealed from Plaintiff that Dr. Durrani served repeated suspensions

for misconduct while Dr. Durrani was still caring for Plaintiff.

9. West Chester/UC Health concealed from Plaintiff that health insurance companies were rejecting payment for BMP-2 leaving Plaintiff unknowingly stuck with a medical bill for a substance they never knew was placed in them.

10. No one from West Chester/UC Health EVER informed Plaintiff of anything negative related to Dr. Durrani before or after the surgery or during Dr. Durrani's treatment of Plaintiff after surgery.

11. Dr. Zeeshan Tayeb signed an affidavit on August 22, 2017 and it is filed in this case. Dr. Tayeb worked for Dr. Durrani while Dr. Durrani had privileges at West Chester/UC Health. The content of that affidavit is as follows:

    a. I worked for Dr. Atiq Durrani as I have detailed in several depositions in the Dr. Durrani malpractice cases for Deters Law.

    b. What was not covered in these depositions was the issue I am addressing in this affidavit. I do so based upon personal knowledge from working with Dr. Durrani's patients and reviewing patient charts after-the-fact.

    c. No matter their medical condition or what the outcome of the surgery, Dr. Durrani, after his patient's surgeries, would always inform those patients it took time to heal no matter the condition or the reason for the condition. I learned after-the-fact from discussions with patients, reviewing patient charts and from investigations that he would make misrepresentations to his patients to keep them from going to other doctors or leaving his care. I believe Dr. Durrani may have done this so his patients would not learn of any malpractice or fraud on his part in performing the surgeries. However, I did not know this until after-the-fact based on discussions with his patients, reviewing patient charts

and from information obtained from investigations.

d. As a post-surgery pain doctor employee on his staff, he used me to treat his post-surgical patients, I believe from my conversations with patients, review of those patient charts and information obtained from investigations that his patients did not suspect Dr. Durrani did anything wrong.

e. I believe based upon my conversation with patients, review of those patient charts an information provided from investigations after-the-fact that patients of Dr. Durrani were left in poor medical condition following surgery. Additionally, I believe these patients may have been deceived by Dr. Durrani into believing that "all was fine." I believe Dr. Durrani to avoid any issues, attempted to and in some cases successfully, convinced patients to believe that he had not done anything wrong, which may have resulted in post-surgery issues experienced by many of his patients.

f. While treating Dr. Durrani's patients, none of the patients ever brought up BMP-2 or PureGen to me. I am unaware whether Dr. Durrani informed his patients that these devices were placed in them. It could be discovered if the patient reviewed the intraoperative reports but I am uncertain if patients ever did this.

12. Dr. Durrani did in fact do C-F on Plaintiff.

13. **Dr. Durrani and West Chester/UC Health intentionally deceived Plaintiff and concealed information in an attempt to avoid civil liability by creating a statute of limitations and/or statute of repose defense.**

14. The statute of limitation and statute of repose issues are all about notice. Dr. Durrani and West Chester/UC Health had NOTICE of what was going on and concealed it from Plaintiffs.

15. From January 2009 through 2013, Dr. Durrani performed 1,823 spinal surgeries at West

Chester/UC Health.

16. Deters Law has over 347 cases against West Chester/UC Health. This means over 19% of Dr. Durrani's surgeries at West Chester/UC Health became a Deters Law case. This is a remarkable statistic, unheard of in medicine or law.
17. There is either attached to Plaintiff's Complaint or filed in the record, a specific comprehensive Affidavit or Merit for this case.
18. Plaintiff had NO reason to believe Dr. Durrani and West Chester/UC Health committed malpractice or fraud upon them or that they concealed it. Until Plaintiff saw the news of Dr. Durrani's arrest in 2013, Plaintiff had no idea what Dr. Durrani might have done at West Chester/UC Health and it was rational or reasonable for Plaintiff, upon seeing Dr. Durrani arrested for unnecessary surgeries to retain Deters Law at that time.
19. On January 30, 2007, on an Ohio Medical Board form necessary for Dr. Durrani to have an Ohio license, Dr. Durrani lied about malpractice awards by denying there were no payments made for him on malpractice cases.
20. From 2009 through the present, West Chester/UC Health was involved in settling Dr. Durrani cases and NEVER reported them to the National Practitioner Bank.

ADDITIONAL ALLEGATIONS ON THE ISSUE OF STATUTE OF LIMITATIONS, STATUTE OF REPOSE AND FRAUD REGARDING CHRIST HOSPITAL

1. Christ Hospital has refused to answer all written discovery requests or schedule depositions in Deters Law Plaintiffs' cases, including this one. There has been NO discovery.
2. From the time of the surgery and/or surgeries Dr. Durrani performed on Plaintiff, to the end of his treatment of Plaintiff, through his flight from the United States in November 2013, Dr. Durrani lied about the outcome of the surgery. Dr. Durrani informed Plaintiff the surgery was successful and perfect, knowing the surgery on Plaintiff was a failure.

3. Dr. Durrani, from the date of his surgery until his flight in November 2013, had a duty to inform Plaintiff of the truth about the unsuccessful surgery and failed to do so.
4. Dr. Durrani also failed to disclose to Plaintiff not only that he placed BMP-2 in Plaintiff without their consent, but he failed to place BMP-2 with the proper cage resulting in ectopic bone growth and other ongoing harm to Plaintiff which is ongoing to this day.
5. Dr. Durrani also lied to Plaintiff about the results of post-op radiology which reflected the failure of the surgery. Nor did he order additional radiology to properly evaluate Plaintiff's condition from after the surgery through his flight in November 2013.
6. Dr. Durrani never revealed hardware failure to Plaintiff from after the surgery through his flight in November 2013.
7. Christ Hospital knew Dr. Durrani practiced all of this deception described in the five prior paragraphs and did not disclose it to the Plaintiff. Christ's duties to Plaintiff with information they knew did not end with Dr. Durrani leaving Christ.
8. Dr. Durrani and Christ Hospital intentionally left BMP-2 off all their consent forms so Plaintiff would not know it was placed in their spine.
9. Christ Hospital concealed from Plaintiff that Dr. Durrani served repeated suspensions for misconduct while Dr. Durrani was still caring for Plaintiff.
10. Christ Hospital concealed from Plaintiff that health insurance companies were rejecting payment for BMP-2 leaving Plaintiff unknowingly stuck with a medical bill for a substance they never knew was placed in them.
11. No one from Christ EVER informed Plaintiff of anything negative related to Dr. Durrani before or after the surgery or during Dr. Durrani's treatment of Plaintiff after surgery.
12. Dr. Zeeshan Tayeb signed an affidavit on August 22, 2017 and it is filed in this case. The

content of that affidavit is as follows:

a. I worked for Dr. Atiq Durrani as I have detailed in several depositions in the Dr. Durrani malpractice cases for Deters Law.

b. What was not covered in these depositions was the issue I am addressing in this affidavit. I do so based upon personal knowledge from working with Dr. Durrani's patients and reviewing patient charts after-the-fact.

c. No matter their medical condition or what the outcome of the surgery, Dr. Durrani, after his patient's surgeries, would always inform those patients it took time to heal no matter the condition or the reason for the condition. I learned after-the-fact from discussions with patients, reviewing patient charts and from investigations that he would make misrepresentations to his patients to keep them from going to other doctors or leaving his care. I believe Dr. Durrani may have done this so his patients would not learn of any malpractice or fraud on his part in performing the surgeries. However, I did not know this until after-the-fact based on discussions with his patients, reviewing patient charts and from information obtained from investigations.

d. As a post-surgery pain doctor employee on his staff, he used me to treat his post-surgical patients, I believe from my conversations with patients, review of those patient charts and information obtained from investigations that his patients did not suspect Dr. Durrani did anything wrong.

e. I believe based upon my conversation with patients, review of those patient charts an information provided from investigations after-the-fact that patients of Dr. Durrani were left in poor medical condition following surgery. Additionally, I believe these patients may have been deceived by Dr. Durrani into believing that "all was fine." I believe Dr.

Durrani to avoid any issues, attempted to and in some cases successfully, convinced patients to believe that he had not done anything wrong, which may have resulted in post-surgery issues experienced by many of his patients.

f. While treating Dr. Durrani's patients, none of the patients ever brought up BMP-2 or PureGen to me. I am unaware whether Dr. Durrani informed his patients that these devices were placed in them. It could be discovered if the patient reviewed the intraoperative reports but I am uncertain if patients ever did this.

13. Dr. Durrani did in fact do C-F on Plaintiff.

14. Dr. Durrani and Christ Hospital intentionally deceived Plaintiff and concealed information in an attempt to avoid civil liability by creating a statute of limitations and/or statute of repose defense.

15. The statute of limitation and statute of repose issues are all about notice. Dr. Durrani and Christ Hospital had NOTICE of what was going on and concealed it from Plaintiffs.

16. There is either attached to Plaintiff's Complaint or filed in the record, a specific comprehensive Affidavit or Merit for this case.

17. Billings by Dr. Durrani is why Christ Hospital allowed Dr. Durrani to do as he chose, regardless of patient harm. The motive was money and greed.

18. Over the years, Christ allowed Dr. Durrani to do surgeries including while Dr. Durrani was employed at Children's, despite having full knowledge of serious issues regarding Dr. Durrani.

19. Plaintiff had NO reason to believe Dr. Durrani and Christ committed malpractice or fraud upon them or that they concealed it. Until Plaintiff saw the news of Dr. Durrani's arrest in 2013, Plaintiff had no idea what Dr. Durrani might have done at Christ and it was rational or reasonable for Plaintiff, upon seeing Dr. Durrani arrested for unnecessary surgeries to retain Deters Law at that time.

20. In 2006, the FDA began releasing to Christ Hospital, all hospitals, Dr. Durrani and all spine surgeons, adverse reports and studies pertaining to BMP-2. This proves that as of 2006, the hospitals knew there were issues relating to BMP-2. Despite that knowledge, and based upon money and greed, Dr. Durrani and Christ still used BMP-2 in Plaintiff and countless other patients.
21. BMP-2 was used in approximately 89.5% of Deters' Christ clients.
22. On January 30, 2007, on an Ohio Medical Board form necessary for Dr. Durrani to have an Ohio license, Dr. Durrani lied about malpractice awards by denying there were no payments made for him on malpractice cases. This includes Christ settlements.
23. From 2000 through 2009, Christ Hospital was involved in settling Dr. Durrani cases and NEVER reported them to the National Practitioner Bank. Had they reported them, Dr. Durrani may have NEVER been able to perform the surgery on Plaintiff and Plaintiff never injured.
24. In July 2012, Christ Hospital paid whistleblower Dr. Peter Podore $1.8 million dollars regarding a cardiologist charging Medicare for vascular tests without reading them.
25. Peter Podore, the former medical director of vascular lab services, claimed tests for up to 8,000 patients were not properly reviewed. The cardiologist involved in the allegations, John Paul Runyon, MD, has left Christ Hospital, but Dr. Podore said hospital administrators ignored warnings about the tests.
26. "Every hospital is going to have problem physicians, problem behavior," Dr. Podore said in the report. "And every hospital has procedures to deal with these things. But my concern is that when a hospital elects to ignore their own internal procedures and in doing so puts patients at risk, that's the problem that sort of forced me to file a claim."
27. The hospital said it has hired a chief compliance officer and plans to "re-review" thousands of

vascular tests, even though federal authorities are not requiring the latter action, according to the report.

28. Dr. Peter Podore called Eric Deters, then legal counsel for Plaintiff in 2013, and informed him Christ Hospital knew about Dr. Atiq Durrani in the same way they knew about Dr. Runyan.
29. Dr. Lee Greiner, spine surgeon at Mayfield, reported to Eric Deters in 2013, Dr. Durrani put a screw through the spine of a male patient and pierced the descending aorta. The patient died in the recovery room at Christ Hospital.
30. Dr. Lee Greiner told the same story to Thomas Atkinson, Deters Law client and Dr. Durrani patient that he told Eric Deters.
31. Despite all of Dr. Durrani's issues at Christ Hospital, Christ Hospital allowed Dr. Durrani to remain there and operate on Plaintiff.
32. Dr. Peter Podore informed Deters Law in 2012 that all the Cincinnati hospitals knew about Dr. Durrani being a problem but they remained silent so he could resign and move from hospital to hospital.
33. The hospitals, including Christ, did the above to avoid reporting them to the NPDB so when the doctors would apply to another hospital, like Dr. Durrani, their record would be clean. This did in fact happen at Christ for Dr. Durrani.
34. Christ Hospital, per Dr. Podore, failed to follow their medical staff bylaws in their management and discipline of Dr. Durrani.
35. Dr. Podore actually served as a vascular surgeon for Dr. Durrani at Christ during spine fusions. After one or two with Dr. Durrani, Dr. Podore told Dr. Durrani he would never work with him again based upon Dr. Durrani's dangerous surgical methods.

36. Dr. Durrani would also misrepresent to Dr. Podore whether someone was a surgical candidate.

37. Dr. Podore stated the hospitals, including Christ, shirk their duty and it is a public safety issue.

INFUSE/BMP-2

I. BACKGROUND INFORMATION

1. The Deters Law Firm, P.S.C., represents approximately 500 Plaintiffs in medical malpractice actions against a former Northern Kentucky/Cincinnati-area spine surgeon named Abubakar Atiq Dr. Durrani (Dr. Durrani), his company, Center for Advanced Spine Technologies, Inc. (CAST), and several area hospitals including, but not limited to, West Chester Hospital (WCH), University of Cincinnati Health (UC Health), Cincinnati Children's Hospital Medical Center (CCHMC), Christ Hospital, Deaconess Hospital, Good Samaritan Hospital and Journey Lite of Cincinnati, LLC (Journey Lite) (collectively Hospitals).
2. Dr. Durrani performed unnecessary, fraudulent, dangerous, and ultimately damaging surgeries on these Plaintiffs while working for and with these Hospitals.
3. The scheme and artifice to defraud that Dr. Durrani devised, executed, and attempted to execute while working for and with the Hospitals included the following patterns and practices:
    a. Dr. Durrani persuaded the patient that surgery was the only option, when in fact the patient did not need surgery.

b. Dr. Durrani told the patient that the medical situation was urgent and required immediate surgery. He also falsely told the patient that he/she was at risk of grave injuries without the surgery.

c. Dr. Durrani often told his cervical spine patients that they risked paralysis or that his/her head would fall off if he/she was involved in a car accident, ostensibly because there was almost nothing attaching the head to the patient's body.

d. Dr. Durrani often ordered imaging studies such as x-rays, CT scans, or MRIs for patients but either did not read or ignored the resulting radiology reports.

e. Dr. Durrani often provided his own exaggerated and dire reading of the patient's imaging study that was either inconsistent with or was plainly contradicted by the radiologist's report. At times, Dr. Durrani provided a false reading of the imaging.

f. Dr. Durrani often dictated that he had performed certain physical examinations and procedures on patients that he did not actually perform.

g. Dr. Durrani often ordered a pain injection for a level of the spine that was inconsistent with the pain stated by the patient or with that indicated by the imaging. Dr. Durrani also scheduled patients for surgeries without learning of or waiting for the results of certain pain injections or related therapies.

h. Dr. Durrani often dictated his operative reports or other patient records months after the actual treatment had occurred.

i. Dr. Durrani's operative reports and treatment records contained false statements about the patient's diagnosis, the procedure performed, and the instrumentation used in the procedure.

j. When a patient experienced complications resulting from the surgery, Dr. Durrani at times failed to inform the patient of, or misrepresented the nature of, the complications.

k. All of the above-mentioned actions were done with the knowledge, cooperation, or intentional ignorance of the Hospitals because Dr. Durrani was one of the biggest moneymakers for the Hospitals.

4. In addition to the civil medical malpractice actions against Dr. Durrani, on August 7, 2013, he was indicted by the Federal Government for performing unnecessary surgeries and for defrauding the Medicare and Medicaid programs. Specifically, the ten-count complaint charged Dr. Durrani with health care fraud, in violation of 18 U.S.C. § 1347, and making false statements in health care matters, in violation of 18 U.S.C. § 1035. There was a subsequent superseding indictment adding over 30 counts.

5. Following these criminal indictments, in December of 2013 and prior to the first Plaintiff's trial in these actions, Dr. Durrani fled the United States and returned to Pakistan. He has not returned to the United States to face allegations of either criminal or civil liability.

6. Among Dr. Durrani's and the Hospitals' professional failings was the use of a synthetic bone-morphogenetic protein called BMP-2, which was marketed under the trade name "Infuse." Dr. Durrani used BMP-2/Infuse in ways that were either not approved by the federal Food and Drug Administration (FDA) or that were specifically contraindicated as noted on the FDA-approved product labeling. The Defendants had full knowledge of this fact.

7. BMP-2/Infuse was, at the time of the surgeries in question, and currently still is manufactured by a company called Medtronic, Inc. (Medtronic).
8. Dr. Durrani predominantly used BMP-2/Infuse on patients at WCH, which is owned by UC Health.
9. It is Plaintiffs' position that this non-FDA-approved use of BMP-2/Infuse was not only negligent, and fraudulent, but criminal based upon the manner in which it was allowed to be used by Dr. Durrani at West Chester, all with the knowledge and full support of the Defendants.

II. THE PLAYERS REGARDING BMP-2

1. Dr. Durrani is a citizen of the Republic of Pakistan and was a permanent resident of the United States who, from approximately 2005 to 2013, worked as a spine surgeon in and around Cincinnati, Ohio, until he fled the United States to escape civil liability and criminal prosecution.
2. Medtronic is an Irish corporation, with its principal executive office located in Dublin, Ireland, and its operational headquarters located in Minneapolis, Minnesota. Medtronic is the world's third largest medical device company and manufactures and markets BMP-2/Infuse. Medtronic sales representatives were also present during the experimental surgeries performed on Plaintiffs, who are clients of the Deters Law Firm.
3. CAST was a corporation organized under the laws of Ohio and had business and medical offices in Florence, Kentucky and Evendale, Ohio. CAST was owned, in whole or in part, by Dr. Durrani.
4. Bahler Medical, Inc. is a manufacturer of medical implants and is a corporation located in the state of Ohio.

5. David Rattigan is an Ohio resident and was and is a sales representative for Medtronic. Further, he is affiliated with Bahler Medical, Inc., was involved in many of the transactions involving BMP-2, and was present for the experimental surgeries in which BMP-2 was used.
6. West Chester Hospital, LLC is a corporation organized under the laws of Ohio. It provides medical facilities and billing support to physicians, including Dr. Durrani, in the state of Ohio. WCH is owned by UC Health.
7. UC Health is a private, non-profit corporation organized under the laws of Ohio. It provides medical facilities, management, administrative, ancillary, and billing support to physicians, and it owns WCH.
8. CCHMC is a medical facility in Ohio where Dr. Durrani was an employee until approximately 2008.

III. WHAT IS BMP-2/INFUSE?

1. The full name of BMP-2 is "Recombinant Human Morphogenetic Protein-2" (also called rhBMP-2). The following definitions apply:
    a. Recombinant – Artificially created in a lab;
    b. Morphogenetic – Evolutionary development of an organism;
    c. Protein – Essential for growth and repair of tissue.
2. Recombinant human protein (rhBMP-2) is currently available for orthopedic usage in the United States.
3. Medtronic manufactured, marketed, sold, and distributed BMP-2 under the trade name "Infuse."
4. BMP-2 has been shown to stimulate the production of bone.

5. Implantation of BMP-2 in a collagen sponge induces new bone formation and can be used for the treatment of bony defects, delayed union, and non-union.

BMP-2 AS A BIOLOGIC

1. BMP-2 is not a device, but instead it is a biologic. *See* July 2009 American Medical Association Article and 2011 Stanford School of Medicine Article.
2. According to the FDA, "[a] 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (Public Health Service Act Sec. 351(i)1." Available at http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm.
3. BMP-2 is a Bone-Morphogenetic Protein that is used to promote bone creation and remolding and falls under the definition of a biologic. *See* AMA article ("bone forming properties") and Stanford Article. BMP-2 differs from a medical device in that once implanted, it can only be removed days after surgery. If a patient had a complication due to BMP-2 and did not discover this complication until year after surgery, the patient could not have BMP-2 removed to reduce the complication because BMP-2 is so integrated into the patient's bone.
4. A patient has a right to determine what happens to his or her body and the preservation of that right requires that the patient be informed when a bone growth product, that causes irreversible harm, is placed in his or her body.

[1] It should be noted that a biologic can also meet the definitions of drug or device. http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm

WHEN IS IT USED?

1. Recombinant human BMPs are used in orthopedic applications such as spinal fusions, non-unions, and oral surgery.
2. The bone graft contains two parts. The first is a solution of human bone growth protein or morphogenetic protein-2. This protein is found in the human body in small dosages and is important for the healing and formation of bones. The protein is genetically engineered to be utilized in the Infuse Bone Graft product, and it is employed for the stimulation of formation and growth in bones.
3. The second part of the bone graft is an absorbable collagen sponge.
4. Both components of the Infuse Bone Graft structure are used to fill the LT-Cage Lumbar Tapered Fusion Device. This chamber is intended to restore the deteriorated disc space to its original height.
5. FDA-approved use for the Infuse Bone Graft product is only for lower back surgery using an anterior lumbar interbody fusion (ALIF), a technique where the operation on the spine is conducted through the abdomen.
6. In addition, the Infuse Bone Graft product must be used in conjunction with Medtronic's LT-Cage. Use of BMP-2 without the LT-Cage is considered an "off-label" use.

CONTRAINDICATIONS OF USE

1. The FDA specifically warns against the use of Infuse in the cervical spine, citing reports of "life-threatening complications."
2. Any use of Infuse other than in lumbar spine surgeries with the LT-Cage is considered "off-label" use

3. Infuse should never be used on the skeletally immature patient, i.e., in patients less than 18 years of age or those with no radiographic evidence of epiphyseal closure.
4. Infuse should never be used in the vicinity of a resected or extant tumor.
5. Infuse should never be used in those patients known to have active infection at the surgical site.

RISKS ASSOCIATED WITH OFF-LABEL USE

1. When used in an off-label manner, patients may experience problems with pregnancy, including but not limited to: complications in fetal development; allergic reactions to titanium, bovine type I collagen, or bone morphogenetic protein–2; infection; the creation or intensification of tumors; liver or kidney disease; lupus or human immunodeficiency virus (HIV/AIDS); problems with radiation, chemotherapy, or steroids if a patient is malignant; paralysis; bowel and/or bladder dysfunctions; sexual disorders, including sterilization and incompetence; respiratory failure; excessive bleeding, and; death.

IV. THE REGULATORY PROCESS

1. The Medical Device Amendments (MDA) to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., established two separate approval processes for medical devices: Pre–Market Approval (PMA) and Pre–Market Notification.[2]
2. The FDA's PMA process is lengthy and involves extensive investigation by the FDA. The PMA application requires manufacturers to submit extensive animal and human data to establish their devices' safety and effectiveness. 21 C.F.R. § 814.20. Frequently, an experimental program under close FDA scrutiny must be successfully completed before

[2] *Fender v. Medtronic*, 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).

FDA approval can be obtained under this process. FDA regulations also require PMA applicants to submit copies of all proposed labeling for the device. 21 C.F.R. § 814.20(b)(10). The FDA approves a PMA application only after extensive review by the agency and an advisory committee composed of outside experts. 21 C.F.R. § 814.40.[3]

3. In contrast, the FDA's Pre–Market Notification process is more abbreviated and involves less FDA oversight. This process requires applicants to submit descriptions of their devices and other information necessary for the agency to determine whether the devices are substantially equivalent. Pre–Market Notification applicants must also submit their proposed labeling. 21 C.F.R. § 807.87. If the FDA determines that a device is substantially equivalent to a device that was on the market prior to the enactment of the MDA in 1976, the applicant is free to market the device.
4. BMP-2 received PMA (PMA number P000058) for the Infuse/BMP-2 Lumbar Tapered Fusion Device, which PMA provided for limited use with specific requirements for its use on individuals. See Medtronic Package Insert.

SCOPE OF THE PMA AND PRODUCT LABELING

1. The PMA for BMP-2 provided that the product may only be used in patients with the following characteristics:
    a. Skeletally mature patient, AND
    b. At levels L2-S1, AND
    c. Confirmed degenerative disc disease (DDD), AND
    d. Using only an open anterior or anterior laparoscopic approach, AND[4]

[3] *Fender v. Medtronic*, 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).
[4] The anterior interbody fusion approach was developed because the risk of non-union (pseudarthrosis) is significantly higher in posterior approaches. The biggest risk factor for fusion surgery is non-union.

e. Six months of non-operative treatment prior to treatment with the device, AND

f. In combination with the metallic LT-CAGE.[5]

See Medtronic Package Insert, "INDICATIONS."

2. According to Medtronic's package insert for BMP-2/Infuse as well as other industry literature, the following risks are associated with the use of BMP-2/Infuse:

a. Male Sterility

b. Cancer

c. Increased progression of cancer

d. Suffocation of the cervical region

e. Bone fracture

f. Bowel/bladder problems

g. Loss of spinal mobility or function

h. Change in mental status

i. Damage to blood vessels and cardiovascular system compromise

j. Excessive bone mass blocking the ability to treat pain

k. Damage to internal organs and connective tissue

l. Death

m. Respiratory problems

n. Disassembly and migration of components

o. Dural tears

p. Ectopic and exuberant bone formation

[5] Instrumented fusions involve hardware and are more stable fusions with a shorter recovery time than non-instrumented fusions.

q. Fetal development complications (birth defects)

r. Foreign body (allergic) reaction

s. Gastrointestinal complications

t. Incisional complications

u. Infection

v. Insufflation complications

w. Neurological system compromise

x. Non-union

y. Delayed union

z. Mal-union

aa. Change in curvature of spine

bb. Retrograde ejaculation

cc. Scars

dd. Tissue and nerve damage

ee. Itching

ff. Pain

gg. Hematoma

hh. Anaphylactic reaction

ii. Elevated erythrocyte sedimentation rate

3. Injury Percentages:

a. Ectopic Bone Growth-63%

b. Inflammatory Neuritis-15%

c. Osteolysis/Subsidence-13%

d. Acute Swelling-7%

e. Retrograde Ejaculation-2%

f. 85% of time, BMP-2 implanted in off-label use

4. Not a single one of these risks in the last two paragraphs were ever explained to a single patient at West Chester by Dr. Durrani.

5. BMP-2 was NOT approved by the FDA for use in the cervical and thoracic spine and BMP-2 was NOT safe or approved for use in children less than 21 years of age. These uses are considered "off-label."

"OFF-LABEL" USE

1. A use of a device is considered "off-label" if it is not approved under the Pre-Market Approval process OR cleared for such use pursuant to 21 U.S.C. § 360c(f) (also known as "the 510k premarket notification process").

2. Infuse can be implanted in an off-label manner in three ways:

   a. Approach/position: Any approach other than an anterior approach;

   b. Product: Failure to use LT-Cage (or any cage); mixing rhBMP-2 with other grafting products like Allograft or Autograft;

   c. Discs: Use on multiple levels or on a level outside of L2-S1.

3. Dr. Durrani and the Hospitals in which he performed surgeries repeatedly used BMP-2 in these non-FDA-approved manners.

THE NON-COMPLIANCE WITH THE REGULATORY PROCESS

1. The PMA 000058 "Conditions of Approval" specifies the following condition: "Before making any change affecting the safety or effectiveness of the device, submit a PMA

supplement for review and approval by the FDA … [a] PMA supplement or alternate submission shall comply with applicable requirements under 21 C.F.R. 814.39[.]"

2. 21 C.F.R. 814.39 requires a PMA supplement pursuant to subsection (a)(1) for new indications of use of the device and pursuant to subsection (a)(6) for changes in components.
3. The PMA 000058 "Conditions of Approval" notes the post-marketing reporting requirement imposed by 21 C.F.R. 814.84, particularly "Identification of changes described in 21 C.F.R. 814.39(a)." Medtronic did not comply with this requirement relating to the intended uses and componentry.
4. The FDA can impose post-approval requirements in the PMA pursuant to 21 C.F.R. 814.82, and this fact results in the device being characterized as "restricted" pursuant to 21 U.S.C. § 360j(e) for purposes of 21 U.S.C. § 352(q). Section 352(q) states that any restricted device that is distributed or offered for sale with false or misleading advertising is "misbranded."
5. "Indications for use" is a necessary part of the PMA application and the "Indications for use" are required to be limited by the application. Any different use is inconsistent with the PMA.
6. A device that fails to meet the requirements of the PMA or 21 C.F.R. 814 is "adulterated" as defined by 21 U.S.C. § 351(f).
7. 21 C.F.R. 801.6 defines a misleading statement related to a DIFFERENT device contained in the label delivered with the device intended to be used will render the device to be used misbranded.

8. Medtronic did not apply for a PMA supplement, as required by the FDA generally and PMA 000058 specifically, for the off-label uses, nor did it provide warnings of the risks known about the off-label uses. All named Defendants in these cases knew about the occurrences of off-label use.
9. The PMA requires an application prior to marketing for new indicated uses by incorporating the federal requirements and explicitly reciting the text of 21 C.F.R. 814.39 and 814.84 and by specifically stating the range of indicated uses on the PMA.

V. MEDTRONIC

1. In or about 2001, Medtronic began preparing for the launch of two spinal fusion products, PYRAMID and INFUSE (BMP-2), which it projected would enjoy broad application with spinal surgeons and their patients on a nationwide basis.
2. Medtronic anticipated that both products would initially be limited in application.
3. Motivated by greed and a desire to gain competitive advantage in the marketplace, Medtronic began a course of conduct designed to broaden the application of both products by end-users. The course of conduct involved fraud, false statements, material misrepresentation, and deceit for the purpose of broadening the sales of these products beyond that which the usual acceptance within the scientific community or regulatory approval would otherwise allow.
4. On or after July 2, 2002, Medtronic received notification that its Pre-Market Approval application for its BMP-2/Infuse bone graft products had been approved by the FDA. However, such approval was limited to the application of the device from the L4 through S1 levels. Further, the approval mandated the conduct of post-approval studies to evaluate the long-term performance of the BMP-2 bone graft and to study the potential side effects

and complications such as the promotion of tumors by the bone morphogenetic protein component of BMP-2. Other studies were conducted as well. See "Allegations against Medtronic in the Unsealed Mississippi False Claims Case."

5. Medtronic engaged in a fraudulent course of conduct designed to maximize its revenues from BMP-2, regardless of whether it would eventually be allowed to remain on the market.

6. One of the physicians Medtronic co-opted into its fraudulent scheme was a Thomas A. Zdeblick, M.D. Dr. Zdeblick was an orthopedic surgeon whose invention, the LT-Cage, was the only approved device to act as the delivery vehicle for BMP-2 into the body.

7. Dr. Zdeblick enjoyed a position within the scientific community as a Key Opinion Leader, and he was both a practicing orthopedic surgeon and professor at the University of Wisconsin.

8. In one of Dr. Zdeblick's first attempts to tout his LT-Cage and rhBMP-2, which would become the active ingredient in the ultimate Infuse/BMP-2 product, he encountered some drawbacks to his goal of promoting his and Medtronic's products, which arose from the policy of certain industry journals, including the journal *Spine*, which followed industry standards before printing peer-reviewed material. See article in the journal *Spine*, published in 2000.

9. Not only were the drawbacks related to industry publishing standards, but the National Consumer Health Information and Health Promotion Act of 1976 enacted certain provisions at 42 U.S.C. § 300u, et seq., whereby the Federal Government had entered the field of medical research publication. Such standards promulgated by the Secretary of the predecessor to the U.S. Department of Health and Human Services required that

applications for grants and contracts must be subject to "appropriate peer review." See 42 U.S.C. § 300u-1.

10. The drawbacks encountered with the peer-reviewed *Spine* article were as follows:
    a. Attribution that the study was "sponsored by Medtronic Sofamor Danek, Inc.;"
    b. The study was conducted under FDA regulations, and was "…designed as a prospective, multicenter, nonblinded, randomized, and controlled pilot study;" and
    c. It was accompanied by a cautionary comment, or Point of View, which minimized the exuberance and import of the article.
11. In the article, BMP-2 was touted by Zdeblick and the co-authors as the potential realization of a dream of Dr. Marshall Urist, a revered pioneer in the industry and discoverer of BMP, where it closed with the following: "…it is encouraging to note that Marshall Urist's seminal observation made more than 34 years ago may finally come to clinical fruition."
12. In the Point of View, a Dr. John O'Brien of London questioned whether there could be long-term problems associated with the product. He treated Zdeblick's study with caution and pointed out that simple plaster of Paris has achieved the same or similar results more than 50 years prior. He posited that, "[p]erhaps vascularization…fixation procedures are as important as the biochemical composition of the 'filler.'"
13. Vascularization is achieved through removal of the disc material between two vertebral bodies and then the scraping of the surfaces of the vertebral bodies in a fusion procedure; fixation is the process of securing the motion segment through medical hardware. In other, if the alternative proposed by Dr. O'Brien proved to achieve equivalent or better results, Zdeblick and Medtronic's Infuse/BMP-2 products would be useless and unnecessary.

14. Certain efforts would follow in an attempt to alleviate the drawbacks encountered with the 2000 *Spine* journal article.

15. In 2002, Dr. Zdeblick was installed as the sole editor-in-chief of a medical journal known prior to his installation as the *Journal of Spinal Disorders*. Prior to his installation, the journal enjoyed a fourteen year history under the co-editorship of Dr. Dan Spangler and Dr. Tom Ducker. Once installed, Dr. Zdeblick successfully supplanted Drs. Dan Spengler and Tom Ducker and became the sole editor-in-chief, a position which would enable him to have greater control and would aid his participation in the fraudulent scheme.

16. During this same time period, Dr. Zdeblick also enjoyed a position on the associate editorial board of the medical journal *Spine*, the leading publication covering all disciplines relating to the spine.

17. In one of Dr. Zdeblick's actions as editor-in-chief, he set about re-purposing the journal in a way that would aid him in the furtherance of the fraudulent scheme through the streamlining of the publication process.

18. In furtherance of the fraudulent scheme, Dr. Zdeblick re-purposed the journal and renamed it the *Journal of Spinal Disorders and Techniques* (JSDT), announcing that the new journal was "entering a new partnership with *Spine*." As part of this partnership, *Spine* would "continue to function as a broad-based scientific journal" tailored to both clinicians and scientists. However, the *Journal of Spinal Disorders and Techniques* would be directed solely to physicians in clinical practice.

19. Dr. Zdeblick's stated goal was "to provide a forum for up-to-date techniques…", and in furtherance of that goal, Dr. Zdeblick announced that his journal would publish Class II or better clinical articles but would "occasionally accept cutting edge articles with less than

one year follow-up." To justify this streamlined process, Dr. Zdeblick claimed as his goal the ability of his journal "to keep up with the fast pace of progress in the treatment of spinal patients."

20. Arm-in-arm with Medtronic and others, Dr. Zdeblick would in short order abuse his position of trust as the editor-in-chief of JSDT.

21. In the October 2002 edition, JSDT published an article entitled, "Anterior Lumbar Interbody Fusion using rhBMP-2 with Tapered Interbody Cages." This article was co-authored by, among others, Curtis A. Dickman, M.D., who was a developer of Medtronic's PYRAMID plate and who has been paid significant sums by Medtronic through royalty agreements, consulting agreements, and education training and speaking agreements.

22. In addition to his interest in the PYRAMID plate, Dr. Dickman had assisted Medtronic in the approval process for Infuse/BMP-2. As part of the pre-approval hearing process, Dr. Dickman and his Barrow Neurological Associates Group of Phoenix, Arizona had submitted a letter to the meeting of the FDA's Orthopedics and Rehabilitation Devices Advisory Panel, which met on January 10, 2002. In that letter, Dr. Dickman represented that "approval of BMP would provide a significant advance for patient outcome and satisfaction following spinal fusion."

23. In the October 2002 issue of JSDT touting the benefits of Infuse/BMP-2, Zdeblick and others failed to disclose their financial ties to Medtronic, though industry standards require such acknowledgement. Not only did Dr. Zdeblick fail to disclose that he profited from each and every surgery which Infuse/BMP-2 was used through rights in the exclusive delivery vehicle, his LT-Cage, but no reference whatsoever to their financial ties to Medtronic was made either by Dr. Zdeblick or Dr. Dickman.

24. For years, the recognized gold standard for spinal bone grafts has been the use of autogenous bone, or bone harvested from the patient's own iliac crest, or hip bone. Medtronic designed to have its Infuse/BMP-2 product supplant autogenous bone as the gold standard in the medical community, and utilized false statements, a fraudulent enterprise and the support of Federal funds to do so.
25. As part and parcel of Medtronic's fraudulent scheme, the October 2002 study was published in Dr. Zdeblick's journal three months after Medtronic received FDA approval for Infuse. As the article shows, it was actually received on March 28, 2002 or after Dr. Zdeblick had accomplished installment as the editor-in-chief, and was accepted by Dr. Zdeblick's journal for publication on July 30, 2002.
26. At the same time Dr. Zdeblick's journal was publishing the initial article on Infuse, Dr. Zdeblick was already finalizing and preparing for subsequent publication a follow-up article to tout Infuse potentially as the new gold standard. A second article, co-authored by Dr. Zdeblick and two other co-authors of the original article, was entitled "Is Infuse Bone Graft Superior to Autograft Bone? An Integrated Analysis of Clinical Trials using the LT-Cage Lumbar Tapered Fusion Device."
27. This second article was published in Vol. 2 of 2003 and once again, there was no mention of Dr. Zdeblick's financial ties to Medtronic.
28. This second article would serve as the second covert advertisement for the Infuse product, and the article states that "the purpose of our analysis was to investigate the potential statistical superiority of Infuse bone graft to autograft…"
29. This second article went on to announce the July 2002 FDA approval of rhBMP-2.

30. This article included as an "acknowledgment" an expression of gratitude to the physicians "who provided patients for this study and to the clinic research group at Medtronic Sofamor Danek for their help in data collection and statistical analyses." However, the article still failed to advise the medical community that some or all of the authors reaching these conclusions touted as monumental had direct financial interests tied to those conclusions.
31. Rather, the failure to report these clear conflicts of interest on the part of those holding positions of trust both within the medical community and over patients was part of Medtronic's fraudulent enterprise. However, unchecked by appropriate peer review, Medtronic was able to systematically accomplish their goals.
32. In its 2003 Annual Report, and without recognizing that Zdeblick was being paid by Medtronic, Medtronic cited to Zdeblick's 2003 as reporting that Infuse "…may become the new gold standard in spinal fusion surgery."
33. By its 2006 Annual Report, if not earlier, Medtronic had removed all doubt, declaring that after its introduction in 2002, "Infuse Bone Graft quickly became the gold standard for certain types of lumbar fusion."
34. Medtronic's fraudulent scheme was successful and resulted in a revenue stream ranging from 700 to 900 million dollars per year.
35. It has been reported that around the same time these stories about Infuse were published, editors at the Spine Journal began receiving complaints from doctors around the country who were pointing out contradictions between papers published by doctors with financial ties to Medtronic and other data involving Infuse complications.' See *Journal Sentinel* article of John Fauber.

36. Through the use of these sham consulting, royalty and education/training agreements with its physician agents in this fraudulent enterprise, Medtronic has reaped windfalls in the billions of dollars. Medtronic has used this fraudulent enterprise and civil conspiracy to drive its vast profits and enhance its market position beyond that which it would have realized without engaging willfully, knowingly and potentially deliberate, conscious, or reckless indifference in the fraudulent enterprise and fraudulent concealment. See Mississippi case.

37. Defendants had full knowledge of all these facts pertaining to Medtronics.

VI. FDA PUBLIC HEALTH NOTIFICATION

1. On July 1, 2008 the FDA issued a Public Health Notification entitled "Life-Threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion."
2. This notification was sent to health care practitioners all across the United States warning of the complications associated with BMP-2, specifically when used in the cervical spine.
3. In the notification the FDA stated they received at least 38 reports of complications during the prior four years with the use of BMP-2 in cervical spine fusions.
4. The complications were associated with swelling of the neck and throat areas, which resulted in compression of the airway and/or neurological structures in the neck.
5. Some reports describe difficulty swallowing, breathing or speaking and severe dysphagia following cervical spine fusion using BMP-2 products had also been reported.
6. The notification further stated that, "since the safety and effectiveness of rhBMP for treatment of cervical spine conditions has not been demonstrated, and in light of the serious

adverse events described above, FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies.

7. The Notification further emphasized the importance of fully informing patients of these potential risks and said that patients treated with BMP-2 in the cervical spine should know:
    a. The signs and symptoms of airway complications, including difficulty breathing or swallowing, or swelling of the neck, tongue, mouth, throat and shoulders or upper chest area
    b. That they need to seek medical attention immediately at the first sign of an airway complication
    c. That they need to be especially watchful 2-14 days after the procedure when airway complications are more likely to occur
    d. rhBMP-2 (contained in Infuse Bone Graft) has received pre-market approval for fusion of the lumbar spine in skeletally mature patients with degenerative disc disease at one level from L2-S1 and for healing of acute, open tibial shaft fractures stabilized with an IM nail and treated within 14 days of the initial injury
8. Additionally, BMP is not approved in any manner for use in patients who are skeletally immature (<18 years of age) or pregnant.
9. Dr. Durrani and the Hospitals ignored ALL of these warnings and used BMP-2 in cervical spine surgeries, children, and those with known compromising factors such as osteoporosis, smoking, and diabetes.
10. Furthermore, the Notification stated that the FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices.

11. The Hospitals that allowed Dr. Durrani to use BMP-2 in their facilities failed to report any complications resulting from his use of BMP-2.

VII. SENATE FINANCE COMMITTEE REPORT

1. Medtronic's actions did not go unnoticed, and in June of 2011 the Senate Finance Committee began an investigation into the fraudulent actions of Medtronic.
2. Medtronic produced more than 5,000 documents pertaining to 13 different studies of BMP-2 for the investigation.
3. On October 25, 2012, Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior member Chuck Grassley (R-Iowa) released the results of their 16-month investigation into Medtronic, which revealed questionable ties between the medical technology company and the physician consultants tasked with testing and reviewing Medtronic products.
4. The investigation revealed that Medtronic employees collaborated with physician authors to edit and write segments of published studies on BMP-2/Infuse without publicly disclosing this collaboration.
5. These fraudulently-produced studies may have inaccurately represented BMP-2's risks and may have placed added weight on the side effects of alternative treatments.
6. The Senate investigation further found that Medtronic also maintained significant, previously undisclosed financial ties with physicians who authored studies about BMP-2, making $210 million in payments to physicians over a 15-year period.
7. Senator Baucus stated, "Medtronic's actions violate the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the

facts the way Medtronic has. Patients everywhere will be better served by a more open, honest system without this kind of collusion."

8. Senator Grassley stated, "The findings also should prompt medical journals to take a very proactive approach to accounting for the content of the articles along with the authorship of the articles and the studies they feature. These publications are prestigious and influential, and their standing rests on rigorous science and objectivity. It's in the interest of these journals to take action, and the public will benefit from more transparency and accountability on their part."

9. Major findings of the investigation include:

    a. Medtronic was involved in drafting, editing and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's role in authoring or substantially editing these articles was not disclosed in the published articles. Medical journals should ensure that any industry role in drafting articles or contributions to authors is fully disclosed.

    b. Medtronic paid a total of approximately $210 million to physician authors of Medtronic-sponsored studies from November 1996 through December 2010 for consulting, royalty and other arrangements.

    c. An e-mail exchange shows that a Medtronic employee recommended against publishing a complete list of adverse events, or side effects, possibly associated with BMP-2/Infuse in a 2005 *Journal of Bone and Joint Surgery* article.

d. Medtronic officials inserted language into studies that promoted BMP-2 as a better technique than an alternative by emphasizing the pain associated with the alternative.

e. Documents indicate that Medtronic prepared one expert's remarks to the FDA advisory panel meeting prior to BMP-2 being approved. At the time, the expert was a private physician but was later hired to be a vice president at Medtronic in 2007.

f. Medtronic documents show the company successfully attempted to adopt weaker safety rules for a clinical trial studying BMP-2 in the cervical spine that would have allowed the company to continue the trial in the event that patients experienced severe swelling in the neck.

VIII. YODA STUDY

1. In response to the various controversies surrounding BMP-2/Infuse, including a June 2011 article in the journal *Spine*, the Yale University Open Data Access (YODA) team reached an agreement for Medtronic to provide full individual participant data from all their trials of rhBMP-2 and allow unrestricted independent re-analysis of this data.
2. The YODA study involved research teams at two universities – the University of York and the Oregon Health and Science University.
3. The review focused exclusively on the use of rhBMP-2 in patients undergoing spinal fusion surgery for treatment of degenerative disc disease, spondylolisthesis, or any other relevant spinal condition.
4. The three main objectives of the study were: 1) to examine the potential benefits of BMP-2, 2) to examine the potential harms of BMP-2, and 3) to assess the reliability of the published evidence base.

5. Medtronic submitted data from 17 studies, including 12 randomized controlled trials (RCTs).
6. In total, the YODA study analyzed the data from 1,409 participants.
7. Though the results showed moderate success with fusions as a result of BMP-2, the study found that BMP-2 results in several different complications including: arthritis, implant-related events, retrograde ejaculation, wound complications, and neurological, urogenital, and vascular events.
8. In regard to the alleged tampering with the peer-reviewed studies by Medtronic, the YODA study found that only two out of twenty peer-reviewed journal publications reported a comprehensive list of all adverse events that occurred during the studies.
9. Furthermore, the way in which adverse event data was presented in the literature was inconsistent, and the rationale for presenting some adverse events but not others was rarely clear.
10. The study concluded that for the period up to 24 months after surgery, treatment with BMP-2 increases the probability of successful fusion (according to Medtronic definitions and reports, which the study noted "were subjective so it is not possible to confirm whether reported successful fusions truly were successful" see YODA Study, p. 35) but this does not translate to clinically meaningful benefits in pain reduction, function, or quality of life. The small benefits in these outcomes observed from six months onward come at the expense of more pain in the immediate post-operative period and a possible increased risk of cancer.
11. Even more relevant to the case against Dr. Durrani and the Hospitals is the YODA study's conclusion that, "[i]t is very important that these findings are expressed clearly and

discussed with patients so that they can make informed choices about the type of surgery they would prefer." *Id.*

12. The University of Oregon Study determined that Infuse/BMP-2 is not better than Autograft, while the University of York study determined that Infuse/BMP-2 offers only a slight and not statistically significant advantage over Autograft.

13. The YODA study concluded that Medtronic "misrepresented the effectiveness and harms through selective reporting, duplicate publication, and underreporting."

14. Adverse event categories such as heterotopic bone formation, osteolysis, and radiculitis were not included in participant databases or internal reports; therefore, the safety profile was not fully assessed.

15. The YODA study further concluded that Medtronic was involved in drafting, editing, and shaping the content of medical journal articles on Infuse/BMP-2 authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's significant role in authoring or substantively editing these articles was not disclosed in the published articles.

16. Medtronic paid a total of approximately $210 million to the physician authors of Medtronic-sponsored studies on Infuse from November 1996 through 2010 for consulting, royalty and other arrangements.

17. An email exchange showed that a Medtronic employee recommended against publishing a complete list of adverse events or side effects possibly associated with Infuse in a 2005 *Journal of Bone and Joint Surgery* article.

18. Medtronic officials inserted language into studies that promoted Infuse as a better technique than an alternative procedure by overemphasizing the pain associated with the alternative procedure.
19. Medtronic's actions violated the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has. See United States Senate Committee on Finance, October 2012.
20. Infuse was intended for a single level anterior lumbar interbody fusion performed with all three components in a specific spinal region. The three components are a tapered metallic spinal fusion cage (NOT PLASTIC), a recombinant human (BMP) bone Morphogenetic Protein, and a carrier/scaffold for the BMP and resulting bone. The Infuse product is inserted into the LT-CAGE Lumbar tapered Fusion Device component to form the complete Infuse Bone Graft/LT–Cage Lumbar Tapered Fusion Device. These components must be used as a system. The Infuse Bone Graft component must not be uses without the LT-Cage Lumbar Tapered Fusion Device component.
21. BMP-2 is not supposed to be used in minors.
22. BMP-2 is not supposed to be used with smokers and diabetics because of vascular slowing.
23. BMP-2 should not be used with women in child bearing years.
24. BMP-2 is contraindicated for patients with a known hypersensitivity to rhBMP-2 and should not be used in the vicinity of a resected or extant tumor, in patients with active malignancy, or in patients undergoing treatment for a malignancy.

IX. DR. DURRANI AND BMP-2

1. Despite all of these warning signs, Dr. Durrani, with the full knowledge of the Defendants, continued to use BMP-2 in ways not approved by the FDA, or in an "off-label" manner.
2. As early as 2007, Dr. Durrani and UC Health knew there were issues with BMP-2 because insurance companies such as Anthem were refusing to pay for BMP-2.
3. Medtronic provided in writing to Dr. Durrani and CAST the approved uses for Infuse/BMP-2.
4. However, Dr. Durrani and the Defendants continued to use BMP-2 in off-label ways, including but not limited to:
    a. Using BMP-2/Infuse in children, despite Medtronic specifically requiring it be used only in "skeletally mature patients;"
    b. Using it outside the L2-S1 level of the spine;
    c. Ignoring the requirement that BMP-2/Infuse only be used for Grade 1 spondylolisthesis or Grade 1 retrolisthesis;
    d. Not requiring at least six months of non-operative treatment prior to the use of BMP-2/Infuse;
    e. Using BMP-2/Infuse without the required cage;
    f. Not using the "carrier scaffold" in conjunction with BMP-2/Infuse as required;
    g. Using BMP-2/Infuse without proper training despite Medtronic's warning, "Caution: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience."
5. Dr. Durrani was a paid consultant for Medtronic.

6. According to Dr. Durrani's own deposition testimony in several cases, Medtronic required one of their representatives to be present in the operating room when its product BMP-2/Infuse is used.
7. Because Medtronic representatives were present in these surgeries, Medtronic knew when Dr. Durrani used BMP-2/Infuse outside the approved uses according to Medtronic's own guidelines.
8. Dr. Durrani was encouraged by Medtronic to obtain peer review and published studies from Medtronic sales representatives to support his use of BMP-2/Infuse.
9. Dr. Durrani was encouraged by Medtronic to be an advocate for his patients and describe how BMP-2/Infuse technology can benefit them.
10. When asked how he got his Medtronic grant, Dr. Durrani responded, "You apply to the Medtronic's corporate and say this is what we want to do, like everybody else in the country applies, and then they come and evaluate the thing and say, "Okay, we think it's worthy. We'll give you the grant."
11. In regard to his role as a Medtronic consultant, Dr. Durrani stated, "If there are certain products that they help us in developing, then they will come to us for a certain consultant role for a certain product development."
12. Dr. Durrani also stated, "I was involved in the development of the minimally invasive spine instrumentation."
13. Dr. Durrani gave conflicting reports on his financial relationship with Medtronic.
14. In a deposition, when asked when his relationship with Medtronic began, Dr. Durrani responded "2000-it's 2003, '04. Something in that category. I'm not sure. It's on the Medtronic website. You can go look at it."

15. Medtronic's website has no information regarding their relationship with Dr. Durrani.
16. In another deposition, Dr. Durrani stated he began his relationship with Medtronic in "2005 or '06."
17. Dr. Durrani also gave conflicting reports on how much compensation he received from Medtronic for his consultation services.
18. In one deposition, Dr. Durrani stated in response to an inquiry as to how much payment he received, "It's a standard compensation. Again, it's on the website, how much they've paid us."
19. Again, this information is not available on the Medtronic website.
20. In another deposition, when asked if he received income from Medtronic, Dr. Durrani replied, "No, I don't."
21. When questioned further if he received a fee as a consultant, he stated, "If you do a work, there is a contractual obligation that they have to pay you. As I told you in my last deposition, they did declare it on their website, so you can actually go on the website and see how much they paid."
22. In another deposition, Dr. Durrani stated that he received, "less than $10,000 in ten years" from Medtronic.
23. An email dated July 30, 2008 from Medtronic Senior Product Manager Katie Stamps to Dr. Durrani states that she "is in the process of working on the renewal of your [Dr. Durrani's] consulting agreement." As stated, this information is not available on Medtronic's website, nor is any information relating to Dr. Durrani's role as a consultant for Medtronic.

24. A CCHMC packet relating to its Orthopedics department indicated that Dr. Durrani received $60,000 in grants, contracts, or industry agreements from Medtronic Sofamor Danek in FY 2008.

25. Financial information discovered concerning Dr. Durrani's relationship with Medtronic was found in Dr. Durrani's biography on the website for the Orthopaedic & Spine Institute, which Dr. Durrani currently operates in Pakistan. The biography states that "Dr. Atiq Dr. Durrani has also received the Clinical Spine Fellowship Grant by the Department of Orthopaedic Surgery which was funded by Medtronic Sofamor Danek with a budget of $59,170 per year." See http://www.osi.com.pk/doctor/dr-atiq-Dr. Durrani-md/.

26. When a request was made to Medtronic regarding its affiliation with Dr. Durrani, the Medtronic Supplier Relations Team stated that Dr. Durrani's "name [is] not listed in our system."

27. Medtronic further responded to the Deters Law Firm's request that the firm would need a "Vendor I.D. Number," which neither Medtronic nor any other party has provided.

28. David Rattigan, Dr. Durrani's main Medtronic representative from Bahler Medical, is actively fighting a subpoena to a give a deposition in these cases.

29. David Rattigan and Medtronic have the same lawyer. Despite the Deters Law Firm's willingness to cooperate in scheduling the date for a deposition, they have refused until recently. Mr. Rattigan's deposition is currently scheduled for the month of June, 2015.

30. In summary, clients of the Deters Law Firm, with the full knowledge and intentional consent of all Defendants, became unsuspecting experiments for real world testing of Medtronic hardware and BMP-2, by and through Dr. Durrani and CAST, who had secret financial connections to Medtronic, improper motives, and submitted false claims. The

government paid for many of these improper and unregulated experiments as a result of the false claims made by Dr. Durrani, with the knowledge of Medtronic, under the veil of "medically necessary" surgeries.

31. Despite repeated requests, Medtronic has refused to cooperate in providing any requested information and is actively downplaying their connections to Dr. Durrani.

X. THE DEFENDANTS AND BMP-2

1. The Defendants allowed and encouraged these practices by Dr. Durrani for the sole purpose of money and greed.
2. David Rattigan was always present in Dr. Durrani's operating rooms as a representative of Medtronic.
3. David Rattigan's sole job was to deliver the BMP-2/Infuse to the Hospitals and make sure that it was inserted correctly into the patient.
4. David Rattigan's presence in the OR further supports the Defendants awareness of Dr. Durrani's fraudulent use of BMP-2/Infuse.
5. UC Health Stored BMP-2 at UC Health Business Center warehouse located in Hamilton County.
6. Dennis Robb, the Senior Vice President of Operations and Chief Supply Officer for UC Health[6] spends $369 million annually and 73% of his budget on contracting[7].
7. Robb was intimately familiar with BMP-2/Infuse and was in charge of acquiring the product for UC Health, which would then keep an inventory of BMP-2/Infuse and supply and distribute it to the Hospitals out of the warehouse as needed.

[6] Robb Deposition Page 8, Brenda Shell Case
[7] Robb Deposition Page 10

8. Robb would place an order with Medtronic, Medtronic would deliver BMP-2/ Infuse to the UC Health Business Center warehouse, and Robb would do a three-way match based on what he ordered, what Medtronic delivered, and the price quoted by Medtronic.
9. The BMP-2/Infuse would be distributed to West Chester from the UC Health Business Center warehouse almost on a daily basis (five to six times a week) based on the inventory demand.
10. UC Health clearly was involved in placing BMP-2/Infuse into the stream of commerce by storing, supplying, and distributing BMP-2/Infuse to its hospitals as needed for surgeries.
11. Despite this awareness, the Defendants NEVER obtained its patients' informed consent regarding the experimental and fraudulent use of BMP-2/Infuse.
12. The **WCH Policy and Procedure Manual** states, in part:

Risk Management: Acknowledgment of Informed Consent. Policy:

No examination or treatment may commence without the consent of the patient or the patient's legally authorized representative.

The principle of informed consent is based on the individual's right to privacy and self-determination, which includes the right to make informed, reasoned decisions concerning one's physical and mental well-being.

It is the responsibility of the treating physician to obtain informed consent.

A nurse may witness the signature of the patient on the Acknowledgment of Informed Consent form if the patient verbalizes an understanding of the procedure, risks, benefits, and alternatives, as explained by the physician.

Informed Consent for surgical or medical procedure and sedation:

a. It is the responsibility of the attending physician to obtain informed consent prior to the procedure. The patient, or his/her representative, will be advised by his/her physician of:

b. The explanation of the procedure

c. The benefits of the procedure

d. The potential problems that might occur during recuperation

e. The risks and side effects of the procedure which could include but are not limited to severe blood loss, infection, stroke or death.

f. The benefits, risks and side effect of alternative procedures including the consequences of declining this procedure or any alternative procedures.

g. The likelihood of achieving satisfactory results

The patient's consent must be documented for:

i. Surgical procedures and invasive procedures
ii. Medical regimens of substantial risk, or that are the subject of human investigations or research must be in writing, and signed and dated by the patient or his/her authorized representative.

13. **WCH/UC Health Policy #ADM.02**, states in part:

a. No examination or treatment may consent without the consent of the patient or the patient's legally authorized representative.

b. The principle of informed consent is based on the individual's right to privacy and self-determination which includes the right to make informed, reasoned decisions concerning one's physical and mental well-being.

c. It is the responsibility of the treating physician to obtain informed consent.

Informed Consent for Surgical or Medical Procedure and Sedation:

It is the responsibly of the attending physician to obtain informed consent prior to the procedure. The patient, or his/her representative, will be advised by his/her physician of:

a. The explanation of the procedure

b. The benefits of the procedure

c. The potential problems that might occur during recuperation

d. The risks and side effects of the procedure which could include but are not limited to severe blood loss, infection, stroke or death.

e. The benefits, risks and side effect of alternative procedures including the consequences of declining this procedure or any alternative procedures.

f. The likelihood of achieving satisfactory results

Completion of the "Consent to Hospital and Medical Treatment" form to examine and treat is NOT sufficient as consent to perform a surgical procedure, invasive procedure, or for medical regimens of substantial risk or that are the subject of human investigation or research.

14. WCH requires its own written consent because it knows its responsibility. It cannot require its own written consent and then "wash its hands" of the responsibility.

15. The Defendants had the responsibility to carry out these consent rules.

16. Dr. Durrani oftentimes used BMP-2 and/or PureGen "off-label" when performing surgeries.

17. BMP-2 is manufactured, marketed, sold and distributed by Medtronic under the trade name "Infuse."

18. Dr. Durrani is a consultant for Medtronic.

19. Defendants did not inform Plaintiff of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.

20. Medtronic, provided in writing to Dr. Durrani and CAST the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

21. BMP-2 is not approved by the Food and Drug Administration for use in the thoracic spine.

22. BMP-2 is neither safe nor approved for use on children less than twenty one (21) years of age.

23. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion

("ALIF" or "Anterior" approach); and only in one area of the spine: L4 to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE")

24. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."
25. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.
26. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.
27. Dr. Durrani, CAST staff and employees, and West Chester/UC Health personnel did not disclose to Plaintiff their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.
28. Dr. Durrani used BMP-2 in Plaintiff in a manner not approved by Medtronic or the FDA.
29. Plaintiff was not informed by Defendants that Dr. Durrani used Infuse/BMP-2 in her surgeries.
30. Plaintiff would not have allowed BMP-2 to be used by Dr. Durrani in her surgeries in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.

31. Plaintiff would not have consented to the use of BMP-2 in her body if informed of the risks by Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.
32. The written informed consent of Dr. Durrani and CAST signed by Plaintiff lacked the disclosure of Infuse/BMP-2's use in her procedures.
33. Plaintiff never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.
34. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.
35. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.
36. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.
37. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.
38. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

PUREGEN NARRATIVE

1. Although Plaintiff did not have PureGen. Plaintiff is providing a PureGen narrative to reflect and relate the overall negligence in the operation of West Chester Hospital.

PUREGEN BACKGROUND

1. PureGen Osteoprogenitor Cell Allograft (PureGen) is a highly concentrated, pure population of Early Lineage Adult (ELA) stem cells that originates in bone marrow and is collected from live, healthy donors.

2. PureGen is harvested from living human beings under the Stem Cell Collection Program administered by the Food and Drug Administration (FDA) and is defined as both a "biologic" by 42 U.S.C. 351(i) and a "drug" as defined by U.S.C. 321(g).
3. PureGen's purpose was to facilitate bone fusion by mimicking the regenerative environment of youthful tissues by increasing the concentration of stem cells available to repair tissue and build bone.
4. When used off-label, as Dr. Durrani often did, biologic bone allograft frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord.
5. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.
6. Alphatec Spine, Inc. is a corporation under the laws of California, and jointly developed and distributed PureGen in the State of Ohio.
7. Alphatec Holdings, Inc. is a holding corporation formed under the laws of Delaware with no operations separate from the holding of other companies which owns Alphatec Spine, Inc.
8. Dirk Kuyper was President and CEO of Alphatec Holdings, Inc. from February 2007 to August 2012.
9. Parcell Laboratories, LLC is organized under the laws of Delaware and jointly developed PureGen.
10. Alphatec and Parcell co-developed the product "PureGen", and both expected PureGen would be initially limited in application.

11. PureGen is produced and distributed by Alphatec Spine, LLC, a division of Alphatec Holdings.
12. PureGen was entered into 3 clinical trials by Alphatec on or around February 9, 2011 which were scheduled to last until September of 2013.
13. The study population were 50 male/female subjects 18 years and older suffering from symptoms of cervical degenerative disc disease in one to four contiguous levels between C3 and T1.
14. The clinical trial required:
    a. Inclusion
        i. Age over 50
        ii. Side-by-side use of PureGen and Autologous bone in the same patient for radiographic comparison
        iii. Symptomatic lumbar degenerative disc disease in up to 2 contiguous levels between L1 and S1
        iv. Subjects with back and/or leg paint indicated for posterior stabilization with or without decompression at any level and posteriolateral fusion
        v. Unresponsive to conservative treatment for at least 6 months
        vi. Radiographic evidence of primary diagnosis
    b. Exclusion:
        i. No healthy volunteers permitted
        ii. More than two levels requiring posteriolateral fusion (PLF)
        iii. Spondylosis greater than Grade 1
        iv. Prior failed fusion surgery at lumbar level(s)

v. Systemic or local infection in the disc or cervical spine, past or present

vi. Active systemic disease

vii. Osteoporosis, Osteomalacia, or other metabolic bone disease that would significantly inhibit bone healing

viii. Use of other bone graft, Bone Morphogenic Protein (BMP), or bone graft substitutes in addition to or in place of those products specified

ix. BMI greater than 40

x. Use of post-operative spinal cord stimulator

xi. Known or suspected history of alcohol and/or drug abuse

xii. Involved in pending litigation or worker's compensation related to the spine

xiii. Pregnant or planning to become pregnant during the course of the study

xiv. Insulin-dependent diabetes mellitus

xv. Life expectancy less than duration of study

xvi. Any significant psychological disturbance that could impair consent process or ability to complete self-assessment questionnaires

xvii. Undergoing chemotherapy or radiation treatment, or chronic use of oral or injected steroids or prolonged use of non-steroidal anti-inflammatory drugs

xviii. Known history of hypersensitivity or anaphylactic reaction to dimethyl sulfoxide (DMSO).

15. All 3 clinical trials were "Terminated" before any results were produced.

16. Alphatec and Parcell saw this limited approval for clinical trials as an opportunity to market PureGen without premarket approval, 510K clearance, an exception to the Food Drug and Cosmetic Act, meeting the humanitarian device exception, investigational new drug (IND) application, or other permission to market PureGen, all in violation of the Food Drug and Cosmetic Act.
17. Alphatec and Parcell began a course of conduct designed to expand the application of PureGen by end users in excess of the approved clinical trial of PureGen. This course of conduct utilized fraud, false statements, material misrepresentation, and deceit in order to broaden the sales of PureGen beyond that which the usual acceptance within the scientific community or regulatory approval would otherwise allow.
18. The Food and Drug Administration (FDA) conducted an inspection of Parcell Laboratories between February 9-14, 2011.
19. After the inspection, the FDA responded quickly to the unlicensed marketing of the device PureGen by warning that PureGen was not the subject of an IND application nor a valid biologics license with a letter dated June 23, 2011.
20. The letter stated that the cells used in the production of PureGen were human cells, tissues, or cellular and tissue-based products (HCT/Ps) as defined in 21 CFR 1271.3(d).
21. Based on this analysis, the FDA determined that PureGen was a drug and biological product as defined in the Federal Food, Drug and Cosmetic Act.
22. According to the Public Health Service Act, a valid biologics license is also required to introduce a biologics device to the market.
23. Alphatec Spine did not acquire a valid biologics license to enter a biologics product into interstate commerce, in violation of 21 U.S.C. 355(a); 42 U.S.C. 262(a).

24. The FDA stated that PureGen, "does not meet all of the criteria in 21 CFR 1271.10(a) and therefore is not regulated solely under section 361 of the Public Health Service Act and the regulations in 21 CFR Part 1271. Specifically, the product does not meet the criterion in 21 CFR 1271.10(a)(4)(ii)(b) because the product is dependent on the metabolic activity of living cells for its primary function."
25. As a result, a valid biologics license was required, which was never obtained by Alphatec or Parcell labs in regards to PureGen. Defendants knew all this.
26. Given this lack of a valid biologics license, the FDA determined that the marketing of PureGen violated both the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.
27. In a statement to the press approximately a week after receiving the FDA Letter, Alphatec President Dirk Kuyper stated, "Both Alphatec Spine and Parcell Laboratories are fully committed to work closely and collaboratively with the FDA to address the questions related to the PureGen Product. We look forward to discussing the PureGen product with the FDA and sharing our clinical outcomes to date." See article "Alphatec comments on FDA's letter regarding PureGen product for spinal fusion procedures", Spinal News International, July 28, 2011, attached as Exhibit E.
28. No such cooperation by Alphatec and Parcell labs occurred and no clinical outcomes were shared with the FDA as all clinical trials of PureGen were "Terminated" and no data was released as to the findings.
29. In fact, Alphatec and Parcell responded to this letter by continuing to market PureGen in an unlicensed manner until Alphatec finally acknowledged the letter in or around February 2013, almost two years after receiving the letter, by stating it disagrees with the

FDA's classification of PureGen as anything other than a tissue product – despite the clinical trial approval listing PureGen as "Biological: PureGen Osteoprogenitor Cell Allograft".

30. Furthermore, according to sales representative, Thomas Blank, Alphatec falsely informed distributors of PureGen that they "resolved" the issues addressed in the FDA letter, did not have to take PureGen off the market and it was "ok" for their distributors to continue marketing and selling PureGen.
31. Despite the approval for the clinical trial of PureGen which limited enrollment to 50 patients, Alphatec advertised in its 2012 Annual Report that PureGen had been implanted in over 3,500 patients.
32. PureGen further stated that it had been placed in these 3,500 patients with "no adverse events related to the product", despite no study, statistics or information to back up such a claim.
33. This 2012 annual report also identified PureGen as a biologic.
34. In the First Quarter of 2011, Alphatec Spine attributed part of its 40.9% increase in revenue to the PureGen product. See Becker's Spine Review, Alphatec Spine Reports $49.7M in Q1 Revenue, 40.9% Increase, May 5, 2011, attached as exhibit H.
35. Eventually, after PureGen had been unlawfully implanted in thousands of patients, Alphatec and Parcell conceded that PureGen is a tissue product and a biologic and stopped shipping PureGen in February of 2013.

PUREGEN AND OHIO LAW

1. It is the position of the Deters Law Firm that the distribution and use of PureGen by Dr. Durrani, Evolution Medical, Alphatec Spine, Inc., and West Chester/UC Health by

Defendants is in violation not only of Federal Law as outlined in the FDA's letter, but Ohio State Law as well.

2. Ohio Revised Code 3715.65(A) states that "No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless an application with respect to the drug has become effective under section 505 of the Federal Food, Drug and Cosmetic Act, 52 Stat. 1040 (1938), 21 U.S.C.A. 301". Defendants violated this provision.
3. A "New Drug" is defined as "Any drug the composition of which is not generally recognized among experts by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof." Ohio Revised Code 3715.01(9)(a).
4. PureGen's status as a Biologic further supports the classification of a drug under the FDA and Ohio Law: "A "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (Public Health Service Act Sec. 351(i)). Additional interpretation of the statutory language is found in 21 CFR 600.3. Biological products also meet the definition of either a drug or device under Sections 201(g) and (h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)." See http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm.
5. It is the position of the Deters Law Firm that PureGen is a drug as defined in ORC 3715.01 and that its distribution before FDA approval was in violation of ORC 3715.65(A). The Defendants with full knowledge and intent violated this statute.

PUREGEN AT THE HOSPITALS

1. On October 10, 2011, UC Health began purchasing PureGen from Alphatec. Thomas Blank was an employee of Innovative Medical Consultants, LLC and a sales representative, seller, marketer, and distributer of PureGen for the Northern Kentucky/Cincinnati area.
2. In his professional capacity, Thomas Blank was present during most, if not all, of the surgeries at issue where PureGen was secretly implanted into various Plaintiffs without informed consent or permission.
3. Thomas Blank worked directly with Alphatec Spine, Inc. and Defendants in the marketing and distribution of PureGen.
4. Additionally, Thomas Blank is a shareholder in Alphatec Spine, Inc.
5. On May 10, 2012 Evolution Medical, LLC, a physician owned distributorship (POD), owned in part (at least 40%) by Dr. Durrani and incorporated in Delaware, received a Kentucky Certificate of Authority.
6. Around this time, Thomas Blank began to work with Evolution Medical in the marketing and distribution of PureGen, in addition to his dealing with Alphatec Spine, Inc.
7. On July 20, 2012, UC Health with the full knowledge and consent of Defendants began purchasing PureGen from Evolution Medical, LLC.
8. The purchase of PureGen, the logistics of the billing, the bills of lading, the receiving and handling of PureGen for West Chester Hospital was handled by UC Health Purchasing.
9. The Defendants tracked West Chester/UC Health's purchases of PureGen from Evolution medical.

10. Specifically, Thomas Blank would provide the materials from Alphatec related to the use and approval of PureGen to Dwayne Brown on behalf of UC Health, who would request PureGen based on the amounts requested by Dr. Durrani and other doctors who used the product.
11. After the UC Health reps approved the use of PureGen, Thomas Blank and his associate Toby Wilcox would order the product, typically in bulk, and draft the requisite billing documents.
12. The PureGen ordered would be stored on site at WCH in the freezer of the operating rooms.
13. In addition to Dr. Durrani, other doctors at WCH used PureGen, including Dr. Chunduri, Dr. Curt and Dr. Shanti.
14. Defendants would purchase and allow these doctors to use a substance not approved by the FDA in patients without their informed consent.
15. Though WCH and UC Health do have patients fill out "informed consent" forms, no mention of PureGen or its non-FDA approved status is mentioned on these forms.

DR. DURRANI AND PUREGEN

1. In one of the few depositions taken of Dr. Durrani before his flight from the country he stated that PureGen is "essentially stem cells" and that he "used to use [PureGen] for a certain amount of time." Deposition of Dr. Durrani in *Brenda Shell v. Durrani*, p. 25-26, attached as Exhibit N.
2. This "certain amount of time" was approximately 3 years between 2010 and 2013, all while PureGen remained unapproved by the FDA.

3. Though downplaying his involvement with PureGen, Dr. Durrani, through his illegal POD Evolution Medical, distributed PureGen to West Chester/UC Health with the full knowledge and consent of Defendants.
4. Dr. Durrani and his Evolution Medical co-owner Toby Wilcox and Defendants, knew the Department of Health and Human Services and the United States Senate Finance Committee has released reports on dangers of Physician-owned entities, notably Physician-owned Distributorships (POD's).
5. Dr. Durrani and Toby Wilcox's actions through Evolution Medical violated the Anti-Kickback Statute 42 U.S.C. 1320 and Stark Law 42 U.S.C. 1395.
6. Compliance with the Anti-Kickback Statutes is a condition of receiving payment from a Federally-funded healthcare program, and most private insurers have a parallel conditional requirement.
7. The Anti-Kickback Statute prohibits the payment and receipt of kickbacks in return for either procuring or recommending the procurement of a good, facility, or item to be paid in whole or in part by a federal healthcare program. 42 U.S.C. 1320a-7b(b).
8. In violation of 45 C.F.R. 46, and in furtherance of the scheme to feign avoidance of the anti-kickback statutes, Dr. Durrani, CAST, Alphatec and the Defendants experimented on patients by using PureGen in unapproved manners, without the informed consent of the patients, and subsequently billing their health insurance companies all while concealing the true nature of their actions.
9. Dr. Durrani also had connections with Alphatec as his personal calendar indicates meetings with Dirk Kuyper, President and CEO of Alphatec in 2008.

10. Dr. Durrani experimentally used PureGen bone graft in twenty cervical surgeries, along with as many as 72 thoracic, cervical, and lumbar surgeries, ignoring the limited uses it was approved for in the clinical trials.
11. Dr. Durrani, through his POD Evolution Medical, was essentially "double dipping" in his dealings with PureGen.
12. Dr. Durrani would sell WCH and the other hospitals the PureGen through Evolution Medical and then use and bill for the PureGen in his surgeries.
13. Dr. Durrani and Defendants knew such an arrangement was either unethical and illegal (though still not disclosing the use of PureGen) by having the patients sign an Acknowledgement of Potential Conflict of Interest form.
14. WCH and Defendant also benefited from this arrangement by up charging patients for the PureGen after purchasing it from Evolution Medical and Dr. Durrani.
15. At all times relevant, Dr. Durrani and Defendants was in exclusive control of the amount and ratio of PureGen bone graft that was experimentally implanted into patients.
16. PureGen was and remains unapproved by the FDA for use in humans without an Investigation New Drug ("IND") or experimental informed consent of the patient.
17. Dr. Durrani and Defendants did not receive experimental informed consent from patients, nor did he verify that an IND was obtained.
18. The basic "Informed Consent Forms" Dr. Durrani and CAST did have patients fill out made no mention of PureGen or the fact a non-FDA approved product was being implanted in their body.

19. In fact, Dr. Durrani and Defendants would even conceal the use of PureGen by intentionally withholding it from the billing records, noting on one Pre-Op Code sheet "Do Not Bill" twice in regards to PureGen.
20. Implanting PureGen in any part of the spinal canal without FDA clearance, proper trials, and patient consent is reckless battery and violates the Hippocratic Oath's statement "I will prescribe regimens for the good of my patients according to my ability and my judgment and never **do harm** to anyone." It is criminal.
21. A majority of the surgeries occurred AFTER the FDA inspection and subsequent warning on the non-FDA approved status of PureGen.
22. Following the cervical surgeries in which PureGen was implanted, the patients' pain became far worse and more extreme.
23. The patients attest to difficulty with swallowing unthickened liquid, medications in pill form, routine saliva, and food.
24. Many patients describe a choking sensation felt on a daily basis when swallowing and changes to the tone and audibility of their voice, along with a chronic cough.
25. Following the thoracic and lumbar surgeries, patients attest to increased spinal pain, difficulty with ambulation, numbness and tingling in lower extremities, decreased flexibility.

IV. CAUSES OF ACTION.

DR. DURRANI COUNTS:

COUNT I: NEGLIGENCE

1. Defendant Dr. Durrani owed his patient, Plaintiff, the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under

like or similar circumstances.

2. Defendant Dr. Durrani breached his duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiff, including but not limited to improper selection for surgery, improper performance of the surgery, and improper follow-up care addressing a patient's concerns.

3. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care on the part of the Defendant Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT II: BATTERY

1. Dr. Durrani committed battery against Plaintiff by performing a surgery that was unnecessary, contraindicated for Plaintiff's medical condition, and for which he did not properly obtain informed consent, inter alia, by using BMP-2 and/or Baxano in ways and for surgeries not approved by the FDA and medical community, and by the failure to provide this information to Plaintiff.

2. Plaintiff would not have agreed to the surgery if they knew the surgery was unnecessary, not approved by the FDA, and not indicated.

3. As a direct and proximate result of the aforementioned battery by Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT III: LACK OF INFORMED CONSENT

1. The informed consent forms from Dr. Durrani which he required Plaintiff to sign failed to fully cover all the information necessary and required for the procedures and surgical procedures performed by Dr. Durrani. Dr. Durrani required an informed consent release.
2. In addition, no one verbally informed Plaintiff of the information and risks required for informed consent at the time of or before Plaintiff's surgery.
3. Dr. Durrani failed to inform Plaintiff of material risks and dangers inherent or potentially involved with her surgery and procedures.
4. Had Plaintiff been appropriately informed of the need or lack of need for surgery and other procedures and the risks of the procedures, Plaintiff would not have undergone the surgery or procedures.
5. As a direct and proximate result of the lack of informed consent, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT IV: INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

1. Dr. Durrani's conduct as described above was intentional and reckless.
2. It is outrageous and offends against the generally accepted standards of morality.
3. It was the proximate and actual cause of Plaintiff's psychological injuries, emotional injuries, mental anguish, suffering, and distress.
4. Plaintiff suffered severe distress and anguish so serious and of a nature that no reasonable man or woman would be expected to endure.

COUNT V: FRAUD

1. The complaint and amended complaints in Warren County Common Pleas Court in *Ruther* did not plead any claim of fraud or a fraud exception to the statute of repose.

2. Plaintiff, based upon all which is pled in this Amended Complaint and Complaint should be entitled to a fraud exception to the statute of repose.
3. Dr. Durrani made material, false representations to Plaintiff and their insurance company related to Plaintiff's treatment including: stating the surgery was necessary, that Dr. Durrani "could fix" Plaintiff, that more conservative treatment was unnecessary and futile, that the surgery would be simple or was "no big deal", that Plaintiff would be walking normally within days after each surgery, that the procedures were medically necessary and accurately reported on the billing to the insurance company, that the surgery was successful, and that Plaintiff was medically stable and ready to be discharged.
4. Dr. Durrani also concealed the potential use of Infuse/BMP-2 in Plaintiff's surgery, as well as other information, when he had a duty to disclose to Plaintiff his planned use of the same.
5. These misrepresentations and/or concealments were material to Plaintiff because they directly induced Plaintiff to undergo her surgery.
6. Dr. Durrani knew or should have known such representations were false, and/or made the misrepresentations with utter disregard and recklessness as to their truth that knowledge of their falsity may be inferred.
7. Dr. Durrani made the misrepresentations before, during and after the surgery with the intent of misleading Plaintiff and their insurance company into relying upon them. Specifically, the misrepresentations were made to induce payment by the insurance company, without which Dr. Durrani would not have performed the surgery, and to

induce Plaintiff to undergo the surgery without regard to medical necessity and only for the purpose of receiving payment.

8. The misrepresentations and/or concealments were made during Plaintiff's office visits at Dr. Durrani's CAST offices.
9. Plaintiff was justified in their reliance on the misrepresentations because a patient has a right to trust their doctor and that the facility is overseeing the doctor to ensure the patients of that doctor can trust the facility.
10. As a direct and proximate result of the aforementioned fraud, Plaintiff did undergo surgery which was paid for in whole or in part by their insurance company, and suffered all damages as requested in the Prayer for Relief.

COUNT VI: SPOLIATION OF EVIDENCE

1. Dr. Durrani willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, emails, billing records, paperwork and related evidence.
2. Dr. Durrani spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.
3. Dr. Durrani's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

WEST CHESTER HOSPITAL/UC HEALTH COUNTS:

COUNT I: NEGLIGENCE

1. Plaintiffs incorporate each and every factual allegation pled in all the prior paragraphs.
2. West Chester Hospital/UC Health owed their patient, Plaintiff, through its agents and employees the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

3. West Chester Hospital/UC Health acting through its agents and employees breached their duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiff, including but not limited to improper selection for surgery, improper performance of the surgery, improper assistance during Plaintiff's surgeries and improper follow up care addressing a patient's concerns.
4. The agents and employees who deviated from the standard of care include nurses, physician assistants, residents and other hospital personnel who participated in Plaintiff's surgeries.
5. The management, employees, nurses, technicians, agents and all staff during the scope of their employment and/or agency of West Chester Hospital/UC Health's knowledge and approval, either knew or should have known the surgery was not medically necessary based upon Dr. Durrani's known practices; the pre-op radiology; the pre-op evaluation and assessment; and the violation of their responsibility under the bylaws, rules, regulations and policies of West Chester Hospital/UC Health.
6. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care by the agents and employees of West Chester Hospital/UC Health, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT II: NEGLIGENT CREDENTIALING, SUPERVISION, AND RETENTION

1. Plaintiffs incorporate each and every factual allegation pled in all the prior paragraphs.
2. By R.C. 2305.251(B) regarding the negligent credentialing of physicians. Therein, it is provided:

a. A Hospital shall be presumed to not be negligent in the credentialing of an individual who has, or has applied for, staff membership or professional privileges at the hospital pursuant to section 3701.351 of the revised code… if the hospital… proves by a preponderance of the evidence that, at the time of the alleged negligent credentialing of the individual, the hospital… was accredited by one of the following:

   i. The joint commission accreditation of healthcare organization;

   ii. The American Osteopathic association;

   iii. The national committee for quality assurance;

   iv. The utilization review accreditation commission.

b. R.C. 2305.251(B)(1)

However, pursuant to R.C. 2305.251, Plaintiff may rebut this presumption against negligence by showing, by a preponderance of the evidence, any of the following:

   i. The credentialing and review requirements of the accrediting organization did not apply to the hospital….the individual, or the type of professional care that is the basis of the claim against the hospital…..

   ii. The hospital failed to comply with all material credentialing and review requirements of the accrediting organization that applied to the individual.

   iii. The hospital through its medical staff executive committee or its governing body and sufficiently in advance to take appropriate action, knew that a **previously competent individual had developed a pattern incompetence or otherwise inappropriate behavior**, either of which indicated that the individual's staff membership, professional privileges, or participation as a

provider should have been limited or terminated prior to the individual's provision of professional care to the Plaintiff.

iv. The hospital through its medical staff executive committee or its governing body and sufficiently in advance to take appropriate action, knew that a previously competent individual would provide **fraudulent medical treatment** but failed to limit or terminate the individual's staff membership, professional privileges, or participation as a provider prior to the individual's provision of professional care to the plaintiff.

3. Defendants negligently credentialed, supervised, and retained Dr. Durrani as a credentialed physician, violating their bylaws and JCAHO rules as fully set forth in this Complaint.
4. The Safe Medical Device Act required entities such as West Chester Hospital/UC Health to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.
5. As a direct and proximate result of the negligent credentialing, supervision, and retention of Dr. Durrani, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT III: FRAUD

1. The complaint and amended complaints in Warren County Common Pleas Court in *Ruther* did not plead any claim of fraud or a fraud exception to the statute of repose.
2. Plaintiff, based upon all which is pled in this Amended Complaint and Complaint should be entitled to a fraud exception to the statute of repose.
3. Plaintiffs incorporates each and every factual allegation pled in all prior paragraphs.

4. Defendants concealed from Plaintiffs facts they knew about Dr. Durrani and made misrepresentations to Plaintiffs as detailed in this Complaint as fully detailed in the paragraphs of this Complaint.
5. Defendant's concealments and misrepresentations were material facts.
6. Defendants had a duty to disclose these material facts to Plaintiffs and a duty to refrain from misrepresenting such material facts to Plaintiffs.
7. Defendants intentionally concealed and/or misrepresented material facts with the intent to defraud Plaintiffs in order to induce Plaintiffs to undergo the surgery or cause them not to decide to cancel surgery, and thereby profited from the surgeries and procedures Dr. Durrani performed on Plaintiffs at West Chester Hospital/UC Health.
8. Plaintiffs were unaware that Infuse/BMP-2 or PureGen would be used in Plaintiffs' surgeries and therefore, were unaware of the health risks of Infuse/BMP-2 or PureGen's use in Plaintiffs' spines.
9. West Chester Hospital/UC Health either concealed from Plaintiff facts they knew about Dr. Durrani, including that Infuse/BMP-2 and/or PureGen would be used in Plaintiff's surgery, or misrepresented to Plaintiff the nature of the surgery, and the particular risks that were involved therein.
10. West Chester Hospital/UC Health's concealments and misrepresentations regarding Infuse/BMP-2 or PureGen and the nature and risks of Plaintiff's surgeries were material facts.
11. Because of its superior position and professional role as a medical service provider, West Chester Hospital/UC Health had a duty to disclose these material facts to Plaintiff and a duty to refrain from misrepresenting such material facts to Plaintiff.

12. West Chester Hospital/UC Health intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgery, and thereby profited from the surgeries and procedures Dr. Durrani performed on Plaintiff at West Chester Hospital/UC Health.
13. Plaintiffs were unaware that Infuse/BMP-2 or PureGen would be used in Plaintiffs' surgeries and therefore, were unaware of the health risks of Infuse/BMP-2 or PureGen's use in Plaintiffs' spines.
14. Had Plaintiff known before Plaintiff's surgeries that Infuse/BMP-2 or PureGen would be used in Plaintiff's spine and informed of the specific, harmful risks flowing therefrom, Plaintiff would not have undergone the surgeries with Dr. Durrani at West Chester Hospital/UC Health.
15. According to Dr. Peter Stern, he knew Dr. Durrani was only "satisfactory" and not a world class surgeon as West Chester advertised.
16. According to Jill Stegman, the risk manager at West Chester, she and others knew Dr. Durrani had "issues".
17. According to former nursing manager, Elaine Kunko, West Chester Hospital knew about Dr. Durrani not completing records and claiming surgeries were emergencies when they were not.
18. Had Plaintiffs known before Plaintiffs' surgeries that Infuse/BMP-2 or PureGen would be used in Plaintiffs' spine and informed of the specific, harmful risks flowing therefrom, Plaintiffs would not have undergone the surgeries with Dr. Durrani at West Chester Hospital/UC Health.

19. West Chester Hospital/ UC Health billed Plaintiff, Lisa Conley, for "OR ALLOGRAFTS" in the amount of $12,401.18 and "OR IMPLANT MISC" in the amount of $15,815.88. Upon information and belief, Plaintiff believes that for "OR ALLOGRAFTS," and "OR IMPLANT MISC" are Infuse/BMP-2 used in Plaintiff's May 26, 2010 surgery.
20. As a direct and proximate result of the fraud upon Plaintiffs by Defendants, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT IV: OHIO CONSUMER SALES PROTECTION ACT

1. Although the Ohio Consumer Sales Protection statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.
2. West Chester Hospital/UC Health's services rendered to Plaintiff constitute a "consumer transaction" as defined in ORC Section 1345.01(A).
3. West Chester Hospital/UC Health omitted suppressed and concealed from Plaintiffs facts with the intent that Plaintiffs rely on these omissions, suppressions and concealments as set forth herein.
4. West Chester Hospital/UC Health's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.
5. West Chester Hospital/UC Health was fully aware of its actions.

6. West Chester Hospital/UC Health was fully aware that Plaintiffs were induced by and relied upon West Chester Hospital/UC Health's representations at the time West Chester Hospital/UC Health was engaged by Plaintiffs.
7. Had Plaintiffs been aware that West Chester Hospital/UC Health's representations as set forth above were untrue; Plaintiffs would not have used the services of the Defendants.
8. West Chester Hospital/UC Health**,** through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.
9. West Chester Hospital/UC Health's actions were not the result of any bona fide errors.
10. As a result of West Chester Hospital/UC Health's unfair, deceptive and unconscionable acts and practices, Plaintiffs have suffered and continues to suffer damages, which include, but are not limited to the following:
    a. Loss of money paid
    b. Severe aggravation and inconveniences
    c. Under O.R.C. 1345.01 Plaintiffs are entitled to:
        i. An order requiring West Chester Hospital/UC Health restore to Plaintiffs all money received from Plaintiffs plus three times actual damages and/or actual/statutory damages for each violation;
        ii. All incidental and consequential damages incurred by Plaintiffs;
        iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred;

COUNT V: PRODUCTS LIABILITY

1. At all times Infuse/BMP-2 and PureGen are and were products as defined in R.C. § 2307.71(A)(12) and applicable law.
2. West Chester Hospital/UC Health (aka supplier) supplied either Medtronic's (aka manufacturer) Infuse/BMP-2 or Alphatec Spine's (aka manufacturer) PureGen for surgery performed by Dr. Durrani on Plaintiff.
3. West Chester Hospital/UC Health, as a supplier, failed to maintain either Infuse/BMP-2 or PureGen properly.
4. West Chester Hospital/UC Health did not adequately supply all components required to use either Infuse/BMP-2 or PureGen properly.
5. West Chester Hospital/UC Health knew or should have known the FDA requirements and Medtronic's requirements for using either Infuse/BMP-2 or PureGen.
6. West Chester Hospital/UC Health stored either Infuse/BMP-2 or PureGen at its facility.
7. West Chester Hospital/UC Health ordered either Infuse/BMP-2 or PureGen for surgery performed by Durrani.
8. West Chester Hospital/UC Health did not adequately warn Plaintiff that either Infuse/BMP-2 or PureGen would be used without all FDA and manufacturer required components.
9. West Chester Hospital/UC Health did not gain informed consent from Plaintiff for the use of either Infuse/BMP-2 or PureGen, let alone warn of the supplying of the product without FDA and manufacturer requirements.
10. West Chester Hospital/UC Health failed to supply either Infuse/BMP-2 or PureGen (aka product) in the manner in which it was represented.

11. West Chester Hospital/UC Health failed to provide any warning or instruction in regard to either Infuse/BMP-2 or PureGen, and failed to make sure any other party gave such warning or instruction.
12. West Chester Hospital/UC Health intentionally billed Infuse/BMP-2 and/or PureGen as "Miscellaneous" to prevent discovery of the use of Infuse/BMP-2 and/or PureGen by Plaintiffs.
13. Plaintiff suffered physical, financial, and emotional harm due to West Chester Hospital/UC Health's violation of the Ohio Products Liability act. Plaintiff's injuries were a foreseeable risk
14. Plaintiff did not alter, modify or change the product, nor did Plaintiff know that the product was being implanted without all required components.
15. West Chester Hospital/UC Health knew or should have known that the product was extremely dangerous and should have exercised care to provide a warning that the product was being used and that the product was being used outside FDA and manufacturer requirements. The harm caused to Plaintiff by not providing an adequate warning was foreseeable,
16. West Chester Hospital/UC Health knew that the product did not conform to the representation of the intended use by the manufacturer yet permitted the product to be implanted into Plaintiff.
17. West Chester Hospital/UC Health, as a supplier, acted in an unconscionable manner in failing to supply the product without all FDA and manufacturer required components.

18. West Chester Hospital/UC Health, as a supplier, acted in an unconscionable manner in failing to warn Plaintiff that the product was being supplied without all FDA and manufacturer required components.
19. West Chester Hospital/UC Health's actions demonstrate they took advantage of the Plaintiffs inability, due to ignorance of the product, to understand the product being implanted without FDA and manufacturer required components.
20. West Chester Hospital/UC Health substantially benefited financially by the use of the product as the product allowed for West Chester Hospital/UC Health to charge more for the surgery.
21. Plaintiff suffered economic loss as defined in R.C. § 2303.71(A)(2) and applicable law.
22. Plaintiff suffered mental and physical harm due to West Chester Hospital/UC Health's acts and omissions.
23. Plaintiff suffered emotional distress due to acts and omissions of West Chester Hospital/UC Health and is entitled to recovery as defined in R.C. § 2307.71(A)(7) and applicable law.
24. West Chester Hospital/UC Health violated the Ohio Products Liability Act R.C. § 2307.71-2307.80
25. West Chester Hospital/UC Health violated R.C. § 2307.71(A)(6)
26. West Chester Hospital/UC Health violated The Ohio Consumer Sales Practices Act R.C. § 1345.02-.03.
27. West Chester Hospital/UC Health provided inadequate warnings are defined in R.C, § 2307.76(A) and applicable law.

COUNT VI: O.R.C. 2923.32 ENGAGING IN A PATTERN OF CORRUPT ACTIVITY; FINES; PENALTIES; FORFEITURE; RECORDS AND REPORTS; THIRD-PARTY CLAIMS TO PROPERTY SUBJECT TO FORFEITURE (State RICO)

1. Pursuant to, O.R.C 2923.32 (A),

> (A)(1) No person employed by, or associated with, any enterprise shall conduct or participate in, directly or indirectly, the affairs of the enterprise through a pattern of corrupt activity or the collection of an unlawful debt.
> (2) No person, through a pattern of corrupt activity or the collection of an unlawful debt, shall acquire or maintain, directly or indirectly, any interest in, or control of, any enterprise or real property.
> (3) No person, who knowingly has received any proceeds derived, directly or indirectly, from a pattern of corrupt activity or the collection of any unlawful debt, shall use or invest, directly or indirectly, any part of those proceeds, or any proceeds derived from the use or investment of any of those proceeds, in the acquisition of any title to, or any right, interest, or equity in, real property or in the establishment or operation of any enterprise.
>
> A purchase of securities on the open market with intent to make an investment, without intent to control or participate in the control of the issuer, and without intent to assist another to do so is not a violation of this division, if the securities of the issuer held after the purchase by the purchaser, the members of the purchaser's immediate family, and the purchaser's or the immediate family members' accomplices in any pattern of corrupt activity or the collection of an unlawful debt do not aggregate one per cent of the outstanding securities of any one class of the issuer and do not confer, in law or in fact, the power to elect one or more directors of the issuer.
>
> Ohio Rev. Code Ann. § 2923.32 (West)

2. The Ohio Revised Code goes on to state that "Person," is defined as, "(G) "Person" means any person, as defined in section 1.59 of the Revised Code, and any governmental officer, employee, or entity." Ohio Rev. Code Ann. § 2923.31 (West)

3. West Chester Hospital, LLC (hereinafter "West Chester Hospital",) was a limited liability

company authorized to transact business and perform medical services in the State of Ohio and operate under the trade name West Chester Hospital.

4. UC Health is the corporate parent, owner and operator of West Chester Hospital, LLC.
5. West Chester Hospital/ UC Health would be considered an entity and according to the Ohio Revised Code definition of a person.
6. The Ohio Revised Code also states that,

   (C) "Enterprise" includes any individual, sole proprietorship, partnership, limited partnership, corporation, trust, union, government agency, or other legal entity, or any organization, association, or group of persons associated in fact although not a legal entity. "Enterprise" includes illicit as well as licit enterprises.

   Ohio Rev. Code Ann. § 2923.31 (West)
7. The Center for Advanced Spine Technologies, Inc. (hereinafter "CAST"), was licensed to and did in fact perform medical services in the State of Ohio, and was and is a corporation authorized to transact business in the State of Ohio and Kentucky.
8. Dr. Durrani was the sole owner of CAST and was directly associated with CAST.
9. CAST is an enterprise.
10. West Chester Hospital/ UC Health was in charge of overseeing Dr. Durrani performed up to par on his patients.
11. Dr. Durrani continued to see new clients and/ or perform unnecessary surgeries, Dr. Durrani performed unnecessary surgeries on the Plaintiffs.
12. West Chester Hospital/ UC Health had knowledge or should have known that Dr. Durrani was performing unnecessary surgeries.

13. West Chester Hospital/ UC Health had knowledge or should have known that Dr. Durrani was categorizing the unnecessary surgeries as "emergencies," and West Chester Hospital/UC Health allowed the surgeries to continue. West Chester Hospital/ UC Health billed for these fraudulent surgeries and aided and conspired with CAST and Dr. Durrani to achieve these acts.
14. West Chester Hospital/ UC Health allowed for Dr. Durrani to perform more unnecessary surgeries and then billed Plaintiffs for those surgeries.
15. Dr. Durrani would see Plaintiffs at his CAST offices.
16. Dr. Durrani would tell Plaintiffs that without surgery, immediately, they would suffer paralysis or death. Plaintiffs would then have the surgery.
17. CAST would schedule the surgery with West Chester Hospital/ UC Health.
18. West Chester Hospital/ UC Health would then allow Dr. Durrani to perform, the unnecessary, surgery on the Plaintiffs and West Chester Hospital/ UC Health would then bill for those unnecessary surgeries.
19. West Chester Hospital/ UC Health allowed for and participated in the fraudulent billing practices, assault due to the unnecessary surgeries, and conspired to aid CAST and Dr. Durrani in these corrupt activities.
20. West Chester Hospital/ UC Health profited from Dr. Durrani's unnecessary surgeries and West Chester Hospital/UC Health billed Plaintiffs for the unnecessary surgeries.
21. West Chester through the fraudulent billing practices and collected unlawful debt collection, from unnecessary surgeries, had an interest in helping CAST continue to lure Plaintiffs into unnecessary surgeries and allow the unnecessary surgeries to occur. This corrupt practice started in May 2009 through at least September 2013, for the purpose of

these particular Plaintiffs.

22. West Chester Hospital/ UC Health, billed Plaintiffs for the unnecessary surgeries, and used the proceeds in the operation of the enterprises.

TCH COUNTS:

COUNT I: NEGLIGENT CREDENTIALING, SUPERVISION, & RETENTION

1. As described in the Counts asserted directly against Dr. Durrani, the actions of Dr. Durrani with respect to Plaintiff constitute medical negligence, lack of informed consent, battery, and fraud.
2. TCH negligently credentialed, supervised, and retained Dr. Durrani as a credentialed physician, violating their bylaws and JCAHO rules in numerous ways, including, but not limited to:
    a. Allowing Durrani to repeatedly violate TCH bylaws with its full knowledge of the same;
    b. failing to adequately review, look into, and otherwise investigate Durrani's educational background, work history and peer reviews when he applied for and reapplied for privileges at TCH;
    c. ignoring complaints about Durrani's treatment of patients reported to it by TCH staff, doctors, patients and others;
    d. ignoring information they knew or should have known pertaining to Durrani's other privileged time at other area hospitals.
3. The Safe Medical Device Act required entities such as TCH to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

4. As a direct and proximate result of the negligent credentialing, supervision, and retention of Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT II: SPOLIATION OF EVIDENCE

1. TCH through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, emails, billing records, paperwork and related evidence.
2. TCH through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.
3. TCH's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

COUNT III: FRAUD

1. The complaint and amended complaints in Warren County Common Pleas Court in *Ruther* did not plead any claim of fraud or a fraud exception to the statute of repose.
2. Plaintiff, based upon all which is pled in this Amended Complaint and Complaint should be entitled to a fraud exception to the statute of repose.
3. TCH sent out billing to Plaintiff at the home following the surgery at TCH.
4. The exact dates these medical bills were sent out are reflected in those medical bills.
5. These bills constituted affirmative representations by TCH that the charges related to Plaintiff's surgery were medically appropriate and properly documented.
6. The bills were sent with the knowledge of TCH that in fact Plaintiff's surgery was not appropriately billed and documented and that the services rendered at TCH associated with Dr. Durrani were not appropriate.

7. The bills sent by TCH to Plaintiff falsely represented that Plaintiff's surgery was appropriately indicated, performed and medically necessary in contra-indication of the standard of care.
8. Plaintiff, Lisa Conley, has requested itemized billing and is still awaiting itemized billing from Christ Hospital.
9. Plaintiff relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiff for TCH's services in association with Dr. Durrani's surgeries.
10. As a direct and proximate result of this reliance on the billing of TCH, Plaintiff incurred medical bills that she otherwise would not have incurred.
11. TCH also either concealed from Plaintiff that they knew about Dr. Durrani, including that Infuse/BMP-2 and/or PureGen would be used in Plaintiff's surgery, or misrepresented to Plaintiff the nature of the surgery and the particular risks that were involved therein.
12. TCH's concealments and misrepresentations regarding Infuse/BMP-2 and/or PureGen and the nature and risks of Plaintiff's surgery were material facts.
13. Because of its superior position and professional role as a medical service provider, TCH had a duty to disclose these material facts to Plaintiff and a duty to refrain from misrepresenting such material facts to Plaintiff.
14. TCH intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgery, and thereby profited from the surgery and procedures Dr. Durrani performed on Plaintiff at TCH.

15. Plaintiff was unaware that Infuse/BMP-2 and/or PureGen would be used in Plaintiff's surgery and therefore, was unaware of the health risks of Infuse/BMP-2 or PureGen's use in Plaintiff's spine.
16. Had Plaintiff known before Plaintiff's surgery that PureGen would be used in Plaintiff's spine and informed of the specific, harmful risks flowing therefrom, Plaintiff would not have undergone the surgery with Dr. Durrani at TCH.
17. As a direct and proximate result of the fraud upon Plaintiff by TCH, Plaintiff sustained all damages requested in the prayer.

COUNT IV: OHIO CONSUMER SALES PROTECTION ACT

1. Although the Ohio Consumer Sales Protection statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.
2. TCH's services rendered to Plaintiff constitute a "consumer transaction" as defined in ORC Section 1345.01(A) and applicable law.
3. TCH omitted suppressed and concealed from Plaintiffs facts with the intent that Plaintiffs rely on these omissions, suppressions and concealments as set forth herein.
4. TCH's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.
5. TCH was fully aware of its actions.
6. TCH was fully aware that Plaintiff was induced by and relied upon TCH's representations at the time TCH was engaged by Plaintiffs.

7. Had Plaintiff been aware that TCH's representations as set forth above were untrue, Plaintiff would not have used the services of Defendants.
8. TCH, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.
9. TCH's actions were not the result of any bona fide errors.
10. As a result of TCH's unfair, deceptive and unconscionable acts and practices, Plaintiff has suffered and continues to suffer damages, which include, but are not limited to the following:
    a. loss of money paid;
    b. severe aggravation and inconveniences;
    c. under ORC 1345.01 Plaintiffs are entitled to
        i. an order requiring TCH restore to Plaintiff all money received from Plaintiff plus three times actual damages and / or actual / statutory damages for each violation;
        ii. all incidental and consequential damages incurred by Plaintiffs
        iii. all reasonable attorneys' fees, witness fees, court cost and other fees incurred.

COUNT V: PRODUCTS LIABILITY

1. At all times Infuse/BMP-2 and PureGen are and were products as defined in R.C. § 2307.71(A)(12) and applicable law.
2. TCH (aka supplier) supplied either Medtronic's (aka manufacturer) Infuse/BMP-2 for surgery performed by Dr. Durrani on Plaintiff.
3. TCH, as a supplier, failed to maintain Infuse/BMP-2 properly.

4. TCH did not adequately supply all components required to use either Infuse/BMP-2 properly.
5. TCH knew or should have known the FDA requirements and Medtronic's requirements for using either Infuse/BMP-2.
6. TCH stored either Infuse/BMP-2 at its facility.
7. TCH ordered either Infuse/BMP-2 for surgery performed by Durrani.
8. TCH did not adequately warn Plaintiff that Infuse/BMP-2 would be used without all FDA and manufacturer required components.
9. TCH did not gain informed consent from Plaintiff for the use of Infuse/BMP-2, let alone warn of the supplying of the product without FDA and manufacturer requirements.
10. TCH failed to supply either Infuse/BMP-2 (aka product) in the manner in which it was represented.
11. TCH failed to provide any warning or instruction in regard to Infuse/BMP-2, and failed to make sure any other party gave such warning or instruction.
12. Plaintiff suffered physical, financial, and emotional harm due to TCH's violation of the Ohio Products Liability act. Plaintiff's injuries were a foreseeable risk
13. Plaintiff did not alter, modify or change the product, nor did Plaintiff know that the product was being implanted without all required components.
14. TCH knew or should have known that the product was extremely dangerous and should have exercised care to provide a warning that the product was being used and that the product was being used outside FDA and manufacturer requirements. The harm caused to Plaintiff by not providing an adequate warning was foreseeable.

15. TCH knew that the product did not conform to the representation of the intended use by the manufacturer yet permitted the product to be implanted into Plaintiff.
16. TCH, as a supplier, acted in an unconscionable manner in failing to supply the product without all FDA and manufacturer required components.
17. TCH, as a supplier, acted in an unconscionable manner in failing to warn Plaintiff that the product was being supplied without all FDA and manufacturer required components.
18. TCH's actions demonstrate they took advantage of the Plaintiff's inability, due to ignorance of the product, to understand the product being implanted without FDA and manufacturer required components.
19. TCH substantially benefited financially by the use of the product as the product allowed for Defendant to charge more for the surgery.
20. Plaintiff suffered economic loss as defined in R.C. § 2303.71(A)(2) and applicable law,
21. Plaintiff suffered mental and physical harm due to TCH's acts and omissions,
22. Plaintiff suffered emotional distress due to acts and omissions of TCH and are entitled to recovery as defined in R.C, § 2307.71(A)(7) and applicable law.
23. TCH violated the Ohio Products Liability Act R.C. § 2307.71-2307.80
24. TCH violated R.C. § 2307.71(A)(6).
25. TCH violated The Ohio Consumer Sales Practices Act R.C. § 1345.02-.03.
26. TCH provided inadequate warnings are defined in R.C, § 2307.76(A) and applicable law.

COUNT VI: O.R.C. 2923.32 ENGAGING IN A PATTERN OF CORRUPT ACTIVITY; FINES; PENALTIES; FORFEITURE; RECORDS AND REPORTS; THIRD-PARTY CLAIMS TO PROPERTY SUBJECT TO FORFEITURE (State RICO)

1. Pursuant to, O.R.C 2923.32 (A)

> (A)(1) No person employed by, or associated with, any enterprise shall conduct or participate in, directly or indirectly, the affairs of the enterprise through a pattern of corrupt activity or the collection of an unlawful debt.
> (2) No person, through a pattern of corrupt activity or the collection of an unlawful debt, shall acquire or maintain, directly or indirectly, any interest in, or control of, any enterprise or real property.
> (3) No person, who knowingly has received any proceeds derived, directly or indirectly, from a pattern of corrupt activity or the collection of any unlawful debt, shall use or invest, directly or indirectly, any part of those proceeds, or any proceeds derived from the use or investment of any of those proceeds, in the acquisition of any title to, or any right, interest, or equity in, real property or in the establishment or operation of any enterprise.
>
> A purchase of securities on the open market with intent to make an investment, without intent to control or participate in the control of the issuer, and without intent to assist another to do so is not a violation of this division, if the securities of the issuer held after the purchase by the purchaser, the members of the purchaser's immediate family, and the purchaser's or the immediate family members' accomplices in any pattern of corrupt activity or the collection of an unlawful debt do not aggregate one per cent of the outstanding securities of any one class of the issuer and do not confer, in law or in fact, the power to elect one or more directors of the issuer.
>
> Ohio Rev. Code Ann. § 2923.32 (West)

2. The Ohio Revised Code goes on to state that "Person," is defined as, "(G) "Person" means any person, as defined in section 1.59 of the Revised Code, and any governmental officer, employee, or entity." Ohio Rev. Code Ann. § 2923.31 (West)
3. Christ Hospital (hereinafter "TCH or Christ,") is a Corporation authorized to transact business and perform medical services in the State of Ohio and operate under the trade name Christ Hospital.
4. "TCH" would be considered an entity and according to the Ohio Revised Code definition of a person.

5. The Ohio Revised Code also states that,

   (C) "Enterprise" includes any individual, sole proprietorship, partnership, limited partnership, corporation, trust, union, government agency, or other legal entity, or any organization, association, or group of persons associated in fact although not a legal entity. "Enterprise" includes illicit as well as licit enterprises.

   Ohio Rev. Code Ann. § 2923.31 (West)

6. Dr. Atiq Abubakar Durrani (hereinafter "Dr. Durrani"), was licensed to and did in fact practice medicine in the State of Ohio.
7. Dr. Durrani received privileges to practice medicine at "TCH". Dr. Durrani was directly associated with "TCH."
8. Dr. Durrani is an enterprise per the definition which specifically states "includes any individual." Dr. Durrani is an enterprise.
9. "TCH" was in charge of overseeing Dr. Durrani performed up to par on his patients.
10. Dr. Durrani continued to see new clients and/ or perform unnecessary surgeries, Dr. Durrani performed unnecessary surgeries on the Plaintiffs at "TCH".
11. "TCH" had knowledge or should have known that Dr. Durrani was performing unnecessary surgeries. Dr. Durrani worked at multiple hospitals before gaining privileges at "TCH." "TCH" should have been or was aware of Dr. Durrani's reputation to perform unnecessary surgeries and yet "TCH" hired Dr. Durrani.
12. "TCH" allowed the surgeries to continue. "TCH" billed for these fraudulent surgeries and aided and conspired with Dr. Durrani to achieve these acts.
13. "TCH" billed for surgeries without itemizing bills and if they did itemize bills they did

not state whether Infuse/BMP-2 or PUREGEN was used but would conceal the use by calling the implant "OR ALLOGRAFT."

14. "TCH" allowed for Dr. Durrani to perform more unnecessary surgeries and then billed Plaintiffs for those surgeries.
15. Dr. Durrani would tell Plaintiffs that without surgery, immediately, they would suffer paralysis or death. Plaintiffs would then have the surgery.
16. "TCH" would then allow Dr. Durrani to perform, the unnecessary, surgery on the Plaintiffs and "TCH" would then bill for those unnecessary surgeries.
17. "TCH" allowed for and participated in the fraudulent billing practices, assault due to the unnecessary surgeries, and conspired to aid Dr. Durrani in these corrupt activities.
18. "TCH" profited from Dr. Durrani's unnecessary surgeries and "TCH" billed Plaintiffs for the unnecessary surgeries.
19. "TCH" through the fraudulent billing practices and collected unlawful debt collection, from unnecessary surgeries, had an interest in helping Dr. Durrani continue to lure Plaintiffs into unnecessary surgeries and allow the unnecessary surgeries to occur. This corrupt practice started in June 2005 through 2009.
20. "TCH" billed Plaintiffs for the unnecessary surgeries, and used the proceeds in the operation of the enterprise.

CAST COUNTS:

COUNT I: VICARIOUS LIABILITY

1. At all times relevant, Defendant Dr. Durrani was an agent, and/or employee of CAST.
2. Dr. Durrani is in fact, the owner of CAST.

3. Defendant Dr. Durrani was performing within the scope of his employment with CAST during the care and treatment of Plaintiff.
4. Defendant CAST is responsible for harm caused by acts of its employees for conduct that was within the scope of employment under the theory of respondeat superior.
5. Defendant CAST is vicariously liable for the acts of Defendant Dr. Durrani alleged in this Complaint including all of the counts asserted against Dr. Durrani directly.
6. As a direct and proximate result of Defendant CAST's acts and omissions, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT II: NEGLIGENT HIRING, RETENTION, AND SUPERVISION

1. CAST provided Dr. Durrani, inter alia, financial support, control, medical facilities, billing and insurance payment support, staff support, medicines, and tangible items for use on patients.
2. CAST and Dr. Durrani participated in experiments using BMP-2 and/or PureGen bone graft on patients, including Plaintiff, without obtaining proper informed consent thereby causing harm to Plaintiff.
3. CAST breached its duty to Plaintiff, inter alia, by not supervising or controlling the actions of Dr. Durrani and the doctors, nurses, staff, and those with privileges, during the medical treatment of Plaintiff at CAST.
4. The Safe Medical Device Act required entities such as CAST to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.
5. Such disregard for and violations of federal law represents strong evidence that CAST negligently hired, retained, and supervised Dr. Durrani.

6. As a direct and proximate result of the acts and omissions herein described, including but not limited to failure to properly supervise medical treatment by Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT III: FRAUD

1. The complaint and amended complaints in Warren County Common Pleas Court in *Ruther* did not plead any claim of fraud or a fraud exception to the statute of repose.
2. Plaintiff, based upon all which is pled in this Amended Complaint and Complaint should be entitled to a fraud exception to the statute of repose.
3. CAST sent out billing to Plaintiff's insurance company after the surgeries at WCH/UC Health.
4. The exact dates these medical bills were sent out are reflected in those medical bills.
5. These bills constituted affirmative representations by CAST that the charges related to Plaintiff's surgeries were medically appropriate and properly documented.
6. The bills were sent with the knowledge of CAST that in fact Plaintiff's surgeries were not appropriately billed and documented and that the services rendered at West Chester Hospital/UC Health associated with Dr. Durrani were not appropriate.
7. The bills sent by CAST to Plaintiff falsely represented that Plaintiff's surgeries were appropriately indicated, performed and medically necessary in contra-indication of the standard of care.
8. Plaintiff relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiff for CAST's services in association with Dr. Durrani's surgery.

9. As a direct and proximate result of this reliance on the billing of CAST, Plaintiff incurred medical bills that she otherwise would not have incurred.
10. CAST also either concealed from Plaintiff that they knew about Dr. Durrani, including that Infuse/BMP-2 and/or PureGen would be used in Plaintiff's surgeries, or misrepresented to Plaintiff the nature of the surgeries, and the particular risks that were involved therein.
11. CAST's concealments and misrepresentations regarding Infuse/BMP-2 and/or PureGen and the nature and risks of Plaintiff's surgeries were material facts.
12. Because of its superior position and professional role as a medical service provider, CAST had a duty to disclose these material facts to Plaintiff and a duty to refrain from misrepresenting such material facts to Plaintiff.
13. CAST intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgeries, and thereby profited from the surgeries and procedures Dr. Durrani performed on Plaintiff at WCH/UC Health.
14. Plaintiff was unaware that BMP-2 and/or PureGen would be used in Plaintiff's surgeries and therefore, was unaware of the health risks of Infuse/BMP-2 and/or PureGen's use in Plaintiff's spine.
15. Had Plaintiff known before Plaintiff's surgeries that Infuse/BMP-2 and/or PureGen would be used in Plaintiff's spine and informed of the specific, harmful risks flowing therefrom, Plaintiff would not have undergone the surgery with Dr. Durrani at West Chester Hospital/UC Health.

16. Upon information and belief, Plaintiff believes the bills requested by Plaintiff will indicate that CAST falsely represented that Plaintiff's surgery was appropriately indicated, performed, and medically necessary in contra-indication of the standard of care.
17. Plaintiff is still awaiting ITEMIZED billing from CAST reflecting the exact totals charged for the use of BMP-2 on Plaintiff.
18. As a direct and proximate result of the fraud against plaintiff by CAST, Plaintiff sustained all damages requested in the prayer for relief.

COUNT IV: OHIO CONSUMER SALES PROTECTION ACT

1. Although the Ohio Consumer Sales Protection statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.
2. CAST's services rendered to Plaintiff constitute a "consumer transaction" as defined in ORC Section 1345.01(A).
3. CAST omitted suppressed and concealed from Plaintiffs facts with the intent that Plaintiffs rely on these omissions, suppressions and concealments as set forth herein.
4. CAST's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.
5. CAST was fully aware of its actions.
6. CAST was fully aware that Plaintiffs were induced by and relied upon CAST's representations at the time CAST was engaged by Plaintiffs.

7. Had Plaintiffs been aware that CAST's representations as set forth above were untrue, Plaintiffs would not have used the services of Defendants.
8. CAST**,** through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.
9. CAST's actions were not the result of any bona fide errors.
10. As a result of CAST's unfair, deceptive and unconscionable acts and practices, Plaintiffs have suffered and continues to suffer damages, which include, but are not limited to the following:
    a. Loss of money paid
    b. Severe aggravation and inconveniences
    c. Under O.R.C. 1345.01 Plaintiffs are entitled to:
        i. An order requiring that CAST restore to Plaintiffs all money received from Plaintiffs plus three times actual damages and/or actual/statutory damages for each violation;
        ii. All incidental and consequential damages incurred by Plaintiffs;
        iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred;

V. PRAYER FOR RELIEF.

WHEREFORE, Plaintiff requests and seeks justice in the form and procedure of a jury, verdict and judgment against Defendants on all claims for the following damages:

1. Past medical bills;

2. Future medical bills;

3. Lost income and benefits;

4. Lost future income and benefits;

5. Loss of ability to earn income;

6. Past pain and suffering;

7. Future pain and suffering;

8. Plaintiff seeks a finding that their injuries are catastrophic under Ohio Rev. Code §2315.18;

9. Plaintiff seeks all relief available under the Ohio Products Liability Act R.C. § 2307.71-2307.80 and applicable law;

10. All incidental costs and expenses incurred as a result of their injuries;

11. The damages to their credit as a result of their injuries;

12. Punitive damages;

13. Costs;

14. Attorneys' fees;

15. Interest;

16. All property loss;

17. All other relief to which they are entitled including O.R.C. 1345.01

Based upon 1-17 itemization of damages, the damages sought exceed the minimum

jurisdictional amount of this Court and Plaintiff seeks in excess of $25,000.

Respectfully Submitted,

/s/ Frederick Johnson
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JURY DEMAND

Plaintiffs make a demand for a jury under all claims.

/s/ Frederick Johnson
Frederick Johnson (0083071)